MedTech Europe
from diagnosis to cure

Compliance Handbook

Overview of national rules on interactions with HCPs and HCOs and status of national transposition of the MedTech Europe Code of Ethical Business Practice

OCTOBER 2017

Introduction

MedTech Europe's Code of Ethical Business Practice lays down clear guidelines for ethical and appropriate interactions of their members with Healthcare Professionals[1]. 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 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:

- Financial support of HCPs (i.e. sponsorship of Healthcare Professionals for attendance at Third Party Organised Educational Conferences)
- Arrangements with consultants
- Hospitality and travel (i.e. meals, accommodation and travel expenses)
- Gifts
- Transparency (i.e. disclosure obligations if applicable)

Disclaimer

The Handbook was prepared by the MedTech Europe Secretariat 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 Handbook is intended for informational purpose only and should not be construed as legal advice for any particular facts or circumstances. MedTech Europe reserves the right to change or amend the overview at any time in order to keep the information up-to-date.

The Handbook shall not, without the prior written consent of MedTech Europe, be disclosed to non-MedTech Europe members.

[1] MedTech Europe Code of Ethics, December 2015: http://www.medtecheurope.org/legal-and-compliance/code

Contents

What's new in this edition

This is the third edition of the Handbook on National Requirements that includes information regarding financial support for HCPs, arrangements with consultants, hospitality and travel, gifts and transparency for both the **medical device and IVD industry** in Europe.

The structure of the Handbook has not changed. However, a number of minor corrections were included, and some references and footnotes were added or updated.

This is a non-exhaustive list of the main changes included in this edition:

- **Belgium**: In June 2017 the Belgian Sunshine Act entered into force. This legislation imposes a legal transparency/disclosure obligation on transfers of value in the medical device industry. It also imposes civil money fines for non-compliance. The first round of data must be uploaded by the end of May 2018.
- **France**: In January 2017 an ordinance was published setting out significant changes to the Anti-Gift Law, including its scope (see section for further details). This ordinance requires the publication of regulations in order to enter into force, which is expected to be published no later than July 2018.
- **Ireland**: The Irish medical technology supply industry (IMSTA) has been added to the Handbook.
- **The Netherlands**: In May 2017 amendments were made to the Dutch Act on Medical Devices, which enter into force on 1 January 2018. The changes prohibit companies from offering business gifts to HCPs.
- **Middle East**: Mecomed approved a new Code of Business Practice, which goes into effect 1 January 2018.
- **Poland**: IPDDL approved a new Code, which went into force on 1 January 2017.
- **Portugal**: In February 2017 the Decree law on Transparency and Publicity of Medical Devices extended the transparency system already in place for medical products to medical devices. It requires all benefits granted to an HCP or entity to be reported to the Portuguese national regulatory authority.
- **Spain**: FENIN approved a new Code of Ethics which contains stricter rules on gifts, setting the limit at EUR 10.
- **Switzerland**: FASMED merged with Medical Cluster to create a new medical technology association called SWISS MEDTECH.
- **Turkey**: In May 2017 the Turkish government indefinitely extended the state of emergency, initially implemented in 2016.
- **UK**: The National Health Service (NHS) published a guidance document setting rules meant to address possible conflicts of interest. Among other things, it sets upper limits for meals and refreshments at 75 £.

Further to this, a chapter about the new MedTech Europe Code of Ethical Business Practice and its main changes have been added to this addition of the Handbook.

MedTech Europe

Updated 25 August 2017

Financial support of HCPs for attendance at Third Party Organised Educational Conferences

The new MedTech Europe Code of Ethical Business Practice[2] ("MTE Code") came into full force on 1 January 2017. However, it provided for a transitional period to allow Member Companies[3] time to phase out direct support of Healthcare Professionals ("HCPs") at Third Party Organized Educational Conferences. After the end of this Transition Period—on 31 December 2017—support of individual HCPs shall no longer be permitted under the new MTE Code. From that point on, Educational Grants become the only way to provide financial support to healthcare professionals to attend Third Party Organised Conferences.

Therefore, until the end of this Transition Period (31 December 2017), direct sponsorship of HCPs is still deemed appropriate and thus, must follow the requirements specified in the MTE Code.

IMPORTANT PLEASE READ

Please note that Direct Sponsorship of HCPs will be banned for **ALL** MedTech Europe Member Companies as of 1 January 2018, even in countries that continue to allow it. While various sections of this Handbook refer to current national association Codes that still allow direct sponsorship, after 31 December 2017 this will **ONLY** apply to non-MedTech Europe member companies.

Any national association section that summarises options for supporting individual HCP's attendance at Third Party Organised Educational Conferences (i.e. direct sponsorship) will not be applicable to any Medtech Europe Member Company as of 1 January 2018. These summaries are simply provided as supplementary information.

The Code defines Educational Grants[4] 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[5]. According to The Code[6], these include Grants provided to support Healthcare Professional participation to Third Party Organised Events. HCPs who benefit from this form of grant are selected by the receiver of the grant rather than the donor. This means that grants can only be provided to legal entities, but never individuals and require a written contract, as well as other related documentation. Member Companies have the ability to define the type of recipients eligible to benefit from the grant, but cannot select individual recipients. These grants will be publicly disclosed by

[2] MedTech Europe Code of Ethical Business Practice (MTE Code), adopted December 2015, please find a pdf version here.
[3] Throughout this Handbook "Member Company" refers to Medtech Europe Members, while "member company" refers to national association members.
[4] MTE Code Part 4 – Glossary and Definitions; MTE Code Part I Chapter 4 Paragraph 3
[5] MTE Code Part I Chapter 4 Paragraph 3
[6] MTE Code Part I Chapter 4 Paragraph 3.a

Member Companies in a central European platform to ensure increased transparency of the funds allocated to medical education[7]. Furthermore, conferences benefitting from an Educational Grant still need to comply with the specific requirements as set out in the Code[8].

Arrangements with Consultants

Beginning on 1 January 2017 the MedTech Europe Code of Ethical Business Practice introduced revised guidelines regarding agreements with consultants. 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 licenced to practice.[9]

It is important to note that, under the new MTE Code, Member Companies are required to implement an independent decision-making/review process when selecting consultants.[10]

In addition to these general criteria for consultancy agreements, the MTE Code lays down specific criteria that must be respected.[11]

Meals, travel and accommodation expenses

Subject to limitation provided in the new MTE Code, Members may provide HCPs with reasonably priced travel, meals and accommodation costs relating to attendance at certain type of events. In these cases, members must assess what is *reasonable* in any given location and regional and country variations will apply. As a general guideline, “reasonable” should be interpreted as the appropriate standard for the given location and must comply with the national laws, regulations and professional codes of conduct.[12] Furthermore, travel expenses may only be reimbursed if they are reasonable and actual and should not cover a period of stay beyond the official duration of the event.[13]

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 licenced. Please find an extensive list of requirements in the MedTech Europe Code of Ethical Business Practice.[14]

[7] MTE Code Part II Chapter 2
[8] MTE Code Chapter 1: General Criteria for Events
[9] MTE Code, Part 1, Chapter 5, Paragraph 1.
[10] MTE Code, Part 1, Chapter 5, Paragraph 1.
[11] A list can be found in the Code, Part 1, Chapter 5, Paragraph 2.
[12] MTE Code, Part 1, Chapter 1, Paragraph 4.
[13] MTE Code, Part 1, Chapter 1, Paragraph 5.
[14] MTE Code, Part 1, Chapter 8.

AUSTRIA

MEDICAL DEVICES: AUSTROMED

Updated: 28 August 2017

General update on the national code

AUSTROMED[15] has revised its Code of Conduct[16] ("AUSTROMED Code) (Verhaltenskodex der AUSTROMED) in line with the new MTE Code, and a new Code came into force on 29 March 2017. This was 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[17].

Procedural highlights

AUSTROMED's Code includes an enforcement mechanism, which provides for a dispute settlement panel known as the Arbitration College[18]. It consists of an external lawyer—who acts as the chair—and two members nominated by the Board and the General Assembly[19]. AUSTROMED also has its Competition Law guidelines available on its website[20].

Financial support of HCPs for attendance at Third Party Organised Educational Conferences

Direct sponsorship of individual HCPs to attend third party scientific events is prohibited. However, Educational Grants are permitted. According to the AUSTROMED Code, written invitations must be addressed to the HCP's employer (e.g. HCO) who will subsequently choose the attendees[21]. The Grant should be limited to registration fees as well as reasonable travel, meals and accommodation costs which have to be documented in writing.

Arrangements with consultants

The requirements regarding arrangements with consultants differ slightly, depending on whether the arrangement concerns consultancy services in general[22] or consultancy services concerning research & development[23].

Arrangements with consultants regarding consultancy services in general are permitted but subject to the following requirements[24]:

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[16] No English version available
[17] Q&As 41-54, Questions and Answers (Q&A) Guidance Document on the AUSTROMED Code (Fragen & Antworten zum AUSTROMED-Kodex), 27 May, 2014
[18] Sec. 20 AUSTROMED Statutes, 22 Nov. 2011
[19] Sec. 14, AUSTROMD Code of Conduct (AUSTROMED Code) (Verhaltenskodex der AUSTROMED), 29 March 2017 ; Sec. 20 AUSTROMED Statutes, 22 Nov. 2011
[20] AUSTROMED Leitfaden zum Kartellrecht (Competition Law Guidelines) (last visited 1 September 2017)
[21] Sec. 7(2)(c), AUSTROMED Code
[22] Sec. 8, AUSTROMED Code
[23] Sec 5, AUSTROMED Code

- 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 the signed contract has to be disclosed to the HCP's employer

The same requirements apply to arrangements regarding research & development, except the written contract has to be approved by the HCOs employer.[25] Please refer to the AUSTROMED Q&A document for further guidance[26].

Meals, travel and accommodation expenses

The Austrian Act on Medical Devices (*Medizinproduktegesetz* or *MPG*)[27] 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[28].

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[29]. Generally, the following rules should apply:

- Accommodation should not normally be provided at top category or luxury hotels or venues known for their entertainment facilities[30];
- Air travel should be economy class unless the duration of the flight extends beyond 5 hours (in which case business class may be considered[31]);
- 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 108 of the MPG, gifts to HCPs are prohibited unless they are of low value and related to the practice of medicine or to medical technology[32]. The MPG does not give any information on what is the minimal value/amount of a permissible gift. However, the AUSTROMED Q&As provide a non-exhaustive[33] list of items that would qualify as permissible low value gifts, including: table or pocket calendars, computer accessories, and various clinical items.

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[24] Sec. 5, AUSTROMED Code
[25] Sec. 5(d), AUSTROMED Code
[26] Q&As 7-14, AUSTROMED Q&A Guidance Document
[27] The Austrian Act on Medical Devices (MPG) (Bundesgesetz betreffend Medizinprodukte - Medizinproduktegesetz - MPG), BGBl I 1996/657
[28] Art. 7, AUSTROMED Code
[29] Q&A36, AUSTROMED Q&A Guidance Document
[30] Q&A35 & 43, AUSTROMED Q&A Guidance Document
[31] Q&A42 & 43, AUSTROMED Q&A Guidance Document
[32] This prohibition is also embodied in the Code, see Section. 10(1), AUSTROMED Code
[33] Q&A16, AUSTROMED Q&A Guidance Document

IN VITRO DIAGNOSTICS: ÖDGH

Updated: 28 August 2017

- ODGH was dissolved on 30 June 2017 and AUSTROMED founded an IVD industry group.[34] Therefore, most of ODGH's members have now become members of AUSTROMED. AUSTROMED is now the only industry association for medical devices and in-vitro diagnostics companies.

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[34] Information available at : http://www.oedgh.at/index.htm. See section above on AUSTROMED for a full discussion of the medtech national requirements in Austria.

BELGIUM

MEDICAL DEVICES & IN VITRO DIAGNOSTICS: BEMEDTECH

Updated: 22 September 2017

General update on the national code

The beMedTech[35] Code of Ethics[36] ("beMedTech Code") (Code d'éthique / Deontologische Code), last amended on 14 May 2014. beMedTech had created a compliance working group, which is in charge of rewriting its Code in line with the MTE Code. The working group will determine the specific manner of transposition over the next few months, with a goal of full implementation by 2020.

Procedural highlights

In order to ensure and enforce compliance with the beMedTech Code, an Ethics Commission was created in 2005. It is composed of external stakeholders (an independent lawyer, four independent experts from the medical technology industry and the director of UNAMEC, who does not have voting rights)[37]. beMedTech does not currently provide any Competition Law Guidelines.

Financial support of HCPs for attendance at Third Party Organised Educational Conferences[38]

For scientific events in Belgium or with Belgian HCPs, which take place over more than one calendar day prior approval by Mdeon[39] (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 be emphasized that this visa application requirement applies to both direct and *indirect* sponsorship (e.g. Educational Grants)[40]. Via the indirect sponsorship route, the visa application is introduced jointly by the HCO and the company[41]. Moreover, the application should be submitted in the name of the sponsoring company, not the HCO[42].

The sponsor and/or organiser should make a request for approval no later than 15 working days before the start of event. The 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

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[35] beMedTech (formerly known as UNAMEC) is the Belgian Trade Association representing companies which manufacture, sell and distribute medical devices: http://www.unamec.be/
[36] There is no English version available.
[37] Arts. 44 & 54 Ch. 5 – Contrôle et sanctions , p 18 beMedTech Code of Ethics (beMedTech Code) (Code d'éthique/Ethische Code), May 2014
[38] These rules apply to all scientific events in Belgium (not only to Third Party Organised Educational Conferences).
[39] Mdeon is a Belgian common ethical platform constituted of 26 associations of physicians, pharmacists, veterinarians, dentists, nurses, paramedical practitioners and of the pharmaceutical and medical devices industry. Mdeon was designated 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 22 September 2017)
[40] 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)
[41] Id. p 1
[42] Id. p 2

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[43]. It is also included in the Mdeon and beMedTech Codes of Ethics[44].

In December 2015 Mdeon published their updated guidelines regarding scientific events which do not require a visa[45].

Arrangements with consultants

According to article 173 of the Code of Conduct of Physicians, MedTech companies are allowed to engage HCP for arrangements. Contracts with physicians must be submitted by a physician for the prior approval of the Physician's Association *(Ordre des médecins (fr) / Orde van geneesheren (nl))*. This obligation concerns only HCPs and not the MedTech companies[46]. The beMedTech Code of Ethics lays down the requirements for arrangements with consultants which are equivalent to the ones of the Eucomed Code[47].

Meals, travel and accommodation expenses

According to the Medicines Act[48], 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;
- 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[49]:

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

In 2012 Mdeon also adopted rules for the travel costs. If the HCP takes part in a scientific event as a participant, the following rules apply[50]:

- Travel by train: Economy or Business Class

[43] Art. 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)
[44] Part II, Chapter II, Mdeon Code of Ethics (Mdeon Code) (Code de déontologie/Code voor deontologie), November 2014; beMedTech Code May 2014
[45] Guidelines relating to Scientific Events not requiring Visa, 17 December 2015, see Mdeon website: www.mdeon.be (Publications / Gifts and events which do not require visa)
[46] Art. 173, Code of Medical Ethics of Physicians' Association (Code de déontologie médicale/ Code van geneeskundige plichtenleer), February 2014: http://www.ordomedic.be/fr/code/chapitre/conventions-avec-des-non-m%E9decins-inventions-et-brevets (last visited 23 September 2017)
[47] Section 5, art.33, beMedTech Code
[48] Art. 10, par. 2, p. 2, Medicines Act
[49] Mdeon Visa Office of 10 October 2014, see Mdeon website: www.mdeon.be (Publications / Case law)
[50] Mdeon Visa Office, see Mdeon website: www.mdeon.be (Communications: maximum amount meals)

- Travel by plane: Always Economy Class (with an exception for consultants, for flights longer than 6 hours)

Gifts

Inexpensive gifts which are related to HCP's practice are allowed[51]. Mdeon published its most recent guidelines relating to gifts in 2016. According to these guidelines[52], 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)

Transparency

At the end of March 2014, the Belgian pharma association (pharma.be) amended its code in order to implement EFPIA's—European Federation of Pharmaceutical Industries and Associations'—disclosure requirements. beMedTech and Mdeon decided to go the same direction[53] and together with pharma.be and several Belgian HCP associations created a common disclosure platform ("betransparent.be"). beMedTech's Code requires that member companies publish on the common disclosure platform value transfers that they make, directly or indirectly, for the benefit of professionals or organizations in the health sector[54]. For premiums and benefits granted in 2016, beMedTech member companies had to disclose these by May 2017[55].

However, with the passage of the Belgian Sunshine Act and its entry into force on 23 June 2017, this disclosure requirement contained in the beMedTech Code was transformed into a legal obligation[56]. Under the Sunshine Act, the first round of data to be notified must be uploaded by 31 May 2018 (to be made public by 30 June 2018) for transfers made since 1 January 2017[57]. Fines for failure to comply with the Sunshine Act could run from 1.600 to 120.000 euros[58]. For further information on this transparency obligation see betransparent.be's FAQs[59]. Gifts (up to 50 euros per benefit) and meals on the other hand are not subject to the disclosure obligations[60].

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[51] Art. 10, par. 2, p. 1, Medicines Act
[52] Premiums and Benefits of Negligible Value: Guidelines, 1 July 2016, see Mdeon website: www.mdeon.be (Publications / Premiums and Benefits of Negligible Value)
[53] Chapter 4: Transparency, beMedTech Code; see also Practical Guidelines for disclosure of Transfers of value, 24 March 2015 (last visited 22 September 2017)
[54] Chapter 4 : Transparency, Art. 40, p 14, beMedTech Code ; see also Practical Guidelines for disclosure of Transfers of value, p 7-8, 24 March 2015 ("*Transfer of value*" includes fees, payments and reimbursements of costs of services and consultancy granted to HCOs/HCPs or POs; contributions to costs of the organization or participation in scientific events such as travel and registration costs granted to HCOs, HCPs, or POs; donations and grants to HCOs; and financial or other support given to POs)
[55] Practical Guidelines for disclosure of Transfers of value, p 7-8, 24 March 2015 ("*Value transfers*" includes fees, payments and reimbursements of costs of services and consultancy granted to HCOs/HCPs or POs; contributions to costs of the organization or participation in scientific manifestations such as travel and registration costs granted to HCOs, HCPs, or POs; donations and grants to HCOs; and financial or other support given to POs)
[56] Arrete royal portant execution du Sunshine Act (Royal Decree of June 14, 2017 implementing the Sunshine Act)
[57] Mdeon has been designated to manage the betransparent.be website; see News : "Mdeon is recognized to manange the transparency platform provided by the Sunshine Act," betransparent.be, 22 August 2017
[58] Frequently Asked Questions Sunshine Act, p 11, betransparent.be, July 2017
[59] Id.
[60] Id. p 6

CZECH REPUBLIC

MEDICAL DEVICES: CZECHMED

Updated: 5 October 2017[61]

General update on the national code

The CzechMed[62] Directive on Cooperation with Healthcare Professionals[63] ("CzechMed Code") (Etický Kodex CzechMed Směrnice o Spolupráci se Zdravotníky) was approved in 2013. CzechMed is currently in discussions with regards to revising its Code.

Procedural highlights

CzechMed's Code is enforced by the Ethics Committee that was created in 2005. It is composed of members of CzechMed and other healthcare stakeholders (Czech Medical Society, Czech Nurse Association and Association of Czech University Hospitals). There is an appeals process available where the Board reviews the acceptability of complaint and further submits it for the review of the Ethics Committee with two new members. CzechMed does not provide Competition Law guidelines.

Financial support of HCPs for attendance at Third Party Organised Educational Conferences

There are no specific legislative rules applicable to the provision of sponsorship of HCPs for attendance at Third Party Organised Educational Conferences. According to the CzechMed Code, its member companies may cover event registration fees as well as reasonable travel, meals and accommodation costs. The event must be primarily focused on the support of appropriate educational and professional activities. Such financial assistance must be in compliance with Czech law and its terms and conditions must be provided prior to the event[64].

Arrangements with consultants

Arrangements with consultants are permitted. The consulting contract has to 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 actually been supplied and conform to the applicable tax laws and other legal requirements[65].

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[61] This was not reviewed by the national association
[62] CzechMed is the Czech Association of Medical Device: http://www.czechmed.cz/
[63] There is no English version available of this document.
[64] Section III, DIRECTIVE ON COOPERATION WITH HEALTHCARE PROFESSIONALS: Supplement to the Code of Ethics of the CzechMed Association (CzechMed Directive) (SMĚRNICE O SPOLUPRÁCI SE ZDRAVOTNÍKY: příloha Etického kodexu asociace CzechMed); 2013
[65] Section V, CzechMed Directive

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 travels 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 being held at five stars 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 stars 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[66]. Gifts

There are no specific legislative rules applicable to the provision of gifts. However, there is a specification of maximum annual amount for gifts to HCPs who can prescribe drugs (applicable for pharma companies)[67]. 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[68].

Transparency

It is important to note that in January 2013 the third version of an Order of the Czech Ministry of Health came into force[69]. 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 of 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.

[66] Section III, CzechMed Directive
[67] ÚST 16, version 1, see here (available in the Czech language only ; last visited 4 October 2017). Maximum amount for gifts per one HCP per calendar year is CZK 1500 / € 60
[68] Section VI, CzechMed Directive
[69] 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.

IN VITRO DIAGNOSTICS: CZEDMA

Updated: 26 September 2017

General update on the national code

The CZEDMA[70] Code of Ethics[71] ("CZEDMA Code") (Etický kodex CZEDMA) was approved in 2008. CZEDMA is currently in the process of revising its Code. During 2017 it has drafted several opinions pertaining to bringing its Code in line with MTE's Code, which will be revised to align with local legislation. Between the end of 2017 and 2018 CZEDMA will present a new draft Code to its General Assembly.

Procedural highlights

The CZEDMA Code is enforced by the Executive Director, in conjunction with the CZEDMA Complaints Office. Parties may send complaints to the CZEDMA Executive Director, who will assess whether they contain sufficient evidence, in which case the complaint is sent to the CZEDMA Complaints Office to be handled[72]. If the decision taken by the Complaints Office is not accepted by the parties, CZEDMA will convene an Independent Council. A further appeal can be lodged in the CZEDMA General Assembly. CZEDMA's Code includes a section on Competition Law and guidelines for compliance[73].

Financial support of HCPs for attendance at Third Party Organised Educational Conferences

According to the current CZEDMA Code, member companies may cover event registration fees as well as reasonable travel, meals and accommodation costs. The event must be primarily focused on the support of appropriate educational and professional activities. Such financial support must be in compliance with Czech law and its terms and conditions must be provided prior to the event. The conference organiser must be responsible for the educational content and the selection of faculty and the sponsoring must be made public in advance and in a clear way[74].

Arrangements with consultants

According to Section IV of the CZEDMA Code HCPs can enter into bona fide consultancy agreements with member companies. The consulting contract has to be in writing, signed by the parties and must specify the services that are to be provided. The contract must be in accordance to applicable legal regulations. Compensation for services rendered must be reasonable and based on the nature of the services being provided. The selection of consultants must be based on their qualifications. Members may pay for reasonable expenses incurred by an HCP when acting as consultant. Members are responsible for gathering all pertinent consents for the HCP to enter in a contractual relation with them.

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[70] CZEDMA is the Czech Association of Manufacturers and Suppliers of In Vitro Diagnostics: http://www.czedma.cz/
[71] There is no English version available.
[72] Part D, Code of Ethics; Czech association of manufacturers and suppliers of in vitro diagnostics (CZEDMA Code) (Etický kodex; Česká asociace výrobců a dodavatelů diagnostik in vitro – CZEDMA), 2008
[73] Part B, CZEDMA Code
[74] Part A, Section II, CZEDMA Code

Meals, travel and accommodation expenses

As mentioned in the Medical Devices part, there are no specific legislative rules applicable to the provision of meals and hospitality. The CZEDMA Code allows the compensation of reasonable travel, meals and accommodation costs, which should always be in line with the nature and time extension of the conference or event.

Financial support must be always in compliance with Czech legislation[75].

Gifts

There are no specific legislative rules applicable to the provision of gifts (please, again, note the gift limits for pharma companies in the medical devices section)[76]. In addition, according to the CZEDMA 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[77].

[75] Sections II and IV, CZEDMA Code
[76] ÚST 16, version 1, available here (only in the Czech language and last visited 26 September 2017). Maximum amount for gifts per one HCP per calendar year is CZK 1500 / € 60
[77] Section V, CZEDMA Code

DENMARK

MEDICAL DEVICES: MEDICOINDUSTRIEN

Updated: 4 October 2017

General update on the national code

The Medicoindustrien Guidelines on Interactions with Healthcare Professionals (Medicoindustrien Guidelines) (Medicoindustriens retningslinjer for samarbejde med sundhedsfagligt personale) were published on 22 November 2010. These Guidelines are a translation of the Eucomed Guidelines on Interaction with Healthcare Professionals, adopted in 2008.

Medicoindustrien is currently engaged in discussions for transposing the MTE Code—more information to come. Please note that until Medicoindustrien approves a new Code, its current Guidelines remain in force.

Procedural highlights

Medicoindustrien does not have a formal enforcement mechanism, but rather handles any dispute through informal discussions and mediation. It also does not have separate Competition Law Guidelines.

Financial support of HCPs for attendance at Third Party Organised Educational Conferences

The Medicoindustrien Guidelines (same as Eucomed[78]) provide that prior written notification to the HCP's employer (or other locally-designated body) is required whenever a member makes a financial contribution to the HCP's medical training. Financial support should be limited to the conference registration fee and reasonable travel, meals and accommodation costs relating to attendance at the event[79].

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. In accordance with the executive order, the Danish HCPs will have to comply with certain reporting obligations when the event takes place outside Denmark[80]. In particular, in such cases, an HCP will have to report certain information to health authorities, e.g. name of the sponsoring company, conference organiser etc. The company will have an obligation to inform HCPs of the reporting requirements at the time of granting the sponsorship.

[78] Medicoindustrien adopted Eucomed Guidelines. Medicoindustrien Guidelines are the translation of the Eucomed Guidelines

[79] Section III, Medicoindustrien Guidelines on Interactions with Healthcare professionals (Medicoindustrien Guidelines) (Medicoindustriens retningslinjer for samarbejde med sundhedsfagligt personale); November 2010

[80] Article 43c of the Drugs Act, in the Consolidation Act no. 506 of 20 April 2013 (lovbekendtgørelse nr. 506 af 20. april 2013)

Arrangements with consultants

The Medicoindustrien Guidelines provide that legitimate consulting arrangements with HCPs should be made in writing and should fully disclose the scope and the object of the agreement. The compensation of the HCP should be fair market value and commensurate to the services provided. The selection of the consultant should be based on the consultant's qualifications and expertise to address the identified purpose[81]. In accordance with the recently revised legislation, HCPs will have to comply with notification or authorisation requirements when engaging in certain arrangements with the industry (see under "Transparency").

Meals, travel and accommodation expenses

It is allowed to cover reasonably priced travel, meals and accommodation costs in connection with the event and in compliance with applicable national and local laws, regulations and professional codes of conducts where the HCP is licensed to practice[82]. Any hospitality should be reasonable in value, subordinate in time and focus to the purpose of the event[83].

Gifts

Occasional modest gifts and branded promotional items of minimal value are accepted and both should be related to the HCP's work. Gifts must not be given in the form of cash or cash equivalents[84].

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)[85]. It is also prohibited to organise competitions (e.g. lottery etc.) in any location.

Transparency

Since November 2014[86], and as part of the revised legislative framework, the Danish Ministry of Health has also adopted a new transparency regime.

The first reporting requirements were submitted in 2016. Medical device companies have to report to the Danish Health and Medicines Authority, 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 Class I products are exempt from these transparency rules.

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[81] Section V, Medicoindustrien Guidelines
[82] Section III, Medicoindustrien Guidelines
[83] Section II, Medicoindustrien Guidelines
[84] Section VI, Medicoindustrien Guidelines
[85] 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.
[86] Order 1154 amending the Medicines Act, the Medical Devices Act, Pharmacies Act, Health Act and the Act for promotionofhealthcare of 26 May 2014 (Lov om ændring af lægemiddelloven, lov om medicinsk udstyr, apotekerloven, sundhedsloven og lov om markedsføring af sundhedsydelser)

The reporting obligation of the company does not include the actual fees paid to the HCP; however, the National Board of Health may request this information at a later stage. The HCPs included in this obligation are doctors, nurses, pharmacists and dentists. These categories of HCPs have the obligation to register or apply for permission regarding their collaborations with Denmark based medical device companies. The HCPs have to report the actual fees received. 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 that take place outside Denmark fall within the scope of the new transparency obligations. The scope of the HCPs under this reporting obligation is even wider: doctors, dentists, pharmacists, nurses, pharmacy assistants, midwives, bioanalysts, 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 on the company in these cases.

IN VITRO DIAGNOSTICS: DIALAB

Updated: 3 October 2017

General update on the national code

The latest version of the DiaLab[87] Code of Conduct[88] ("DiaLab Code") (Etiske retningslinjer) was published in August 2014. Further to this, DiaLab has Rules for Exhibitions (Regler for udstilinger) which provide guidelines for product information, exhibitions, advertising and sponsorships at scientific conferences and educational events.

DiaLab does not currently have plans to transpose the MTE Code.

Procedural highlights

DiaLab does not have an enforcement mechanism for its Code nor does it provide Competition Law guidelines.

Financial support of HCPs for attendance at Third Party Educational Conferences

DiaLab's Code[89] does not impose specific limits in these areas; however, as discussed above, in 2014 The Danish Ministry of Health revised the legislative framework for interactions between pharmaceutical companies and HCPs. Please see above for a summary of these obligations.

Arrangements with consultants

See above

Meals, travel and accommodation expenses

See above

Gifts

Please note that the meaning of "insignificant value" in regards to gifts as explained in the medical devices section for Denmark also applies for the In Vitro Diagnostics industry, and therefore gifts should not be of higher value than DKK 300 (around EUR 40).

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.

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[87] DiaLab is the Danish diagnostics and laboratories industry association. http://www.dialab.dk/
[88] There is no English version available.
[89] DiaLab Code of Conduct (Dialab Code) *(Etiske Retningslinjer)*, last amended August 2014

FINLAND

MEDICAL DEVICES& IN VITRO DIAGNOSTICS: SAILAB

Updated: 29 September, 2017

General update on the national code

Sailab recently underwent a name change and the association is now called Sailab-MedTech Finland ("Sailab"). The Sailab[90] Ethical Guidelines (Sailab Code) (*Sai-Lab Eettiset ohjeet*) were published on 21 September 2005. There is also an English version available and further to this Sailab had previously adopted the Eucomed Guidelines on Interactions with HCPs in November 2011.

In spring 2017, Sailab established an Ethical Code working group to begin discussions on transposition of the MTE Code. In the fall it will send a proposed Finnish Ethical Code to the Sailab Board. The proposed Code will then have to be approved by the Board and subsequently by the Sailab General Assembly. If the Code is approved by both, Sailab's new Code will go into force on 1 January 2018 and would provide for a one (1) year transition period. This new Code will be published in Finnish.

Procedural highlights

Sailab's current Code does not provide for an enforcement mechanism. Additionally, Sailab does not provide Competition Law guidelines.

Financial support of HCPs for attendance at Third Party Organised Educational Conferences

Until Sailab approves a new Code, its current one continues to apply[91]. However, it is important to highlight that Sailab's current Code already does not recommend direct sponsorship of HCPs[92]. In particular, any invitation to educational events must be addressed to the healthcare organisation the HCP works for[93].

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[94].

[90] The Finish association of laboratory and healthcare product suppliers: http://www.sailab.fi/
[91] Sailab adopted Eucomed Guidelines on Interaction with Healthcare Professionals in November 2009.
[92] Ethical Guidelines (Sailab Code) (Eettiset ohjeet): Education and training; September 2005
[93] 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.
[94] Section V, Eucomed Guidelines

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[95].

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[96].

[95] Section III, Eucomed Guidelines
[96] Section VI, Eucomed Guidelines

FRANCE

MEDICAL DEVICES: SNITEM

Updated: 28 September, 2017

General update on the national code

The SNITEM Ethics Charter ("SNITEM Code") (*Charte éthique et deontologie profesionelle du SNITEM*)[97] was approved in January 2011. SNITEM does plan a revision of its Ethics Charter. However, due to upcoming changes in French legislation further details on a timeline will be forthcoming.

Procedural highlights

SNITEM's Code is currently enforced by the Ethics Commission and the SNITEM Board, consisting of association members and a former key figure of the industry. SNITEM does not provide any Competition Law guidelines.

Financial support of HCPs for attendance at Third Party Organised Educational Conferences

Before entering into any professional activity involving HCPs, companies must seek a prior opinion of the competent professional board[98]. This requirement also applies for the indirect sponsorship of HCPs' attendance to Third Party Organised Educational Conferences. The company must notify the indirect sponsorship project in due time to the competent professional board[99] in order to obtain a prior opinion as to the compliance of this project with article L. 4113-6 of the FCPH. Such prior-notification must be made at least one month before the relevant event. The file submitted must contain certain information[100], which must, therefore, be provided by the Professional Conference Organiser ("PCO")/HCO to the company, once the PCO/HCO has selected the HCPs to be sponsored.

The opinion from the professional board is not legally binding – in theory a negative opinion does not prevent the company from maintaining the concerned sponsorship[101]. However, in practice courts obviously take into account the opinions issued so companies are strongly encouraged to follow them.

Hospitality granted indirectly to HCPs must be of a reasonable value and strictly limited to the professional/scientific purpose of the event. Moreover, it cannot be extended to persons who are not directly concerned by the event. These conditions should be indicated under the grant agreement to be concluded with the PCO/HCO.

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[97] There is no English version available
[98] Obligation provided by article L. 4113-6 of the French Code of Public Health (FCPH) (*Code de la santé publique*)
[99] For events taking place at national or international level, the most relevant one for MedTech Europe members is the National Medical Board (CNOM – *Conseil national de l'Ordre des médecins*)
[100] The draft agreement laying out the expenses paid (or a letter of invitation to the HCP), the event program, the list of the HCP sponsored and the nature and amount of each expenses (Article R. 4113-105 of FCPH). This information must, therefore, be provided to the company by the PCOs, in advance of the event
[101] In case of a negative opinion, the company must inform the HCP concerned (Article R.4113-107 of the FCPH)

The Bertrand Law[102] has introduced a notification obligation for the companies, requiring them to notify the relevant board whether the hospitality agreement with HCPs was eventually implemented. This must be done within one month after the implementation (i.e. after the date of the event)[103].

Arrangements with consultants

The provisions of article L. 4113-6 of FCPH also apply for the arrangements with consultants. Companies must submit all agreements concluded with HCPs for a prior opinion of the competent professional board before their implementation. This must be done at least two months prior to implementation for research/scientific evaluation activities[104] and at least one month in relation to all other agreements. In addition, the Bertrand Law introduced a new notification obligation for the companies requiring notifying the competent professional board whether the agreement was eventually implemented. This must be done within one month after the implementation (i.e. after the effective date of the agreement)[105].

HCPs who practice at public hospitals in France must obtain authorisation to enter into agreements for carrying secondary activities from the institution (and, as the case maybe, the university) to which the public HCPs belong[106]. The boards now request a copy of this authorisation (or at least a proof of the request of such authorisation) and issue negative opinions in cases where the authorisation is not delivered, either by the HCP or by the company. It should be noted that this authorisation is not included in the list of documents to be provided for prior opinion under the French Anti-Gift law[107].

To be compensated by healthcare companies, HCPs must be registered as “independent workers” and, therefore, must have an “URSSAF” number, or if they are public agents, must be paid as “assimilated employees”. Companies may also use the services of *"société de portage"* (services providers) which will employ the non-URSSAF employees for the time of the services to be rendered, however, some professional boards issue negative opinions on agreements entered into via such *société de portage*.

Meals, travel and accommodation expenses reimbursed or paid to consultants

Meals, travel and accommodation expenses may be reimbursed to consultants. Such expenses must be reasonable, and must be indicated into the draft agreement submitted for prior opinion to the relevant professional board.

Improvised meals under normal working relationship

“Normal working relationships” are an exception to the Anti-Gift Law. There is no legal definition of *normal working relationships*, but the professional board generally accepts that companies invite HCPs for lunch (without having to comply with the prior opinion procedure) if such meal is

[102] Law n° 2011-2012 dated December 29, 2011 relating to the enhancing of health safety of medicinal drugs and health products (LOI n° 2011-2012 du 29 décembre 2011 relative au renforcement de la sécurité sanitaire du médicament et des produits de santé)
[103] Article R. 4113-107-1 of FCPH
[104] Article R. 4113-107 of FCPH. The documents to be included in the file submitted to the relevant board are provided under Article R. 4113-105 of FCPH
[105] Article R. 4113-107-1 of the FPHC
[106] According to Article 4 of decree n°2007-658 of May 2, 2007 related to the holding of several activities of officials, of non-public rights holders, agents and industrial state establishment workers
[107] “Anti-Gift Law” (Loi anti-cadeaux) introduced in 1993 and amended by the Bertrand Law of 29 December 2011

"improvised" (not planned in advance), not excessive and not-repeated. It should correspond to exceptional situations which are accessory to HCPs' normal activities. Companies are strongly advised to define the conditions of such normal working relationships under the internal policies.

Gifts

As a general rule, gifts are forbidden[108] unless the following conditions are satisfied[109]:

- Insignificant value: gifts of a maximum EUR 30 (VAT excl.) per HCP per year per industry are allowed; and
- Related to the HCP's practice. For example, under the case law, a bottle of wine is considered inappropriate because it is not related to HCP's medical practice.

It is not acceptable to offer a cash advance in any form[110].

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An ordinance published on 19 January 2017 makes significant changes to the French Anti-Gift Law. The ordinance requires the publication of regulations in order for it to enter into force. The regulations should be published no later than 1st July 2018.

The modifications are:

- All companies manufacturing or commercialising health products or providing health services will be bound by the new rules. The scope of the future Anti-Gift Law will, therefore, cover any company manufacturing or marketing health products, regardless of whether or not payment for the products is reimbursed under the French social security system.

- All HCPs will be covered, whereas currently only some HCPs are concerned.

- Societies will also be covered.

- The future Anti-Gift Law will clarify what benefits will be specifically excluded from its scope. For example, exceptions would include remuneration, compensation, and reimbursement of expenses provided by an employment contract and relating exclusively to the exercise of the HCP's professional activities; or benefits related to the exercise of the HCP's professional activities, provided that the amounts concerned are of a negligible value.

- The amounts of acceptable fees, grants and hospitality will be defined by the regulations. Companies willing to offer higher amounts will have to request a prior authorisation from the relevant authority. Below, a declaration will have to be made.

- The formalities will be made on line.

[108] Obligations of Anti-Gift Law are laid down under Articles L. 4113-6, R. 4113-104 of the FCPH
[109] Joint LEEM, Snitem (the French MedTech Association) and CNOM Document for Guidance on the Application of art. L.4113-6 (Document d'Orientation d'Interprétation et d'Application de l'article L.4113-6 du code de la santé publique), June 21, 2007

- The penalties incurred for non-compliance with the requirements will be increased from the current fine of up to €375,000 to a fine of up to €750,000. Alternatively, the fine could be up to 50 per cent of the expenses incurred in carrying out any practice constituting an offence.

Transparency

In addition to all these requirements, the Bertrand Law introduced disclosure/transparency rules. In particular, article L.1453-1 was introduced under the FCPH which imposed a two-fold obligation on companies: on one hand, to disclose the existence of agreements concluded between healthcare companies and HCPs/other stakeholders as specified under article L.1453-1 of the FPHC; and on the other hand, to declare the value of all advantages, in kind or in cash, such stakeholders receive from healthcare companies (above or equal to 10 EUR including VAT). The decree relating to transparency regulations was published on 21 May 2013[111]. This decree was supplemented by the ministerial circular of 29 May 2013 specifying the scope of its provisions[112]. In accordance with the law, in June 2014 the French Ministry of Social Affairs and Health launched a public database[113].

All relationships with HCPs, as described above, must be published by healthcare companies in the public database. The new Law on modernisation of the health system also lead to the amendment of L. 1453-1 which led to stricter disclosure rules.

It is important to note that the original circular excluded remunerations from the information to be published[114]. This has changed after a judgement of the French Council of State *(Conseil d'Etat)*[115], which deemed that clause null and void. As a consequence, MedTech companies must disclose all remunerations dating back to the original entry into force of the Law, that is, January 1, 2012. To address this problem, the new Law on modernisation of the health system provides a legal framework for the publication of the remunerations. Decree no. 2016-1939 of December 28, 2016 clarifies the modalities through which companies manufacturing or marketing health care products in France must now report detailed information on contracts (such as the indirect and final beneficiary of a contract[116]) as well as remunerations or fees granted to health care professionals. This much-awaited decree finally clarifies the French Sunshine regime, in force since 2012, which had been partially overruled by the *Conseil d'Etat* in 2015 and modified by the Touraine Law of January 26, 2016.

Please be aware, that healthcare companies must also comply with data protection requirements regarding transparency (information of HCPs, formalities to the French data protection authority in case of data transfer to a non-European country).

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[111] The implementing decree n° 2013-414 dated May 21, 2013 relating to the transparency obligations of the companies manufacturing or selling sanitary or cosmetic products for human beings (Décret n° 2013-414 du 21 mai 2013 relatif à la transparence des avantages accordés par les entreprises produisant ou commercialisant des produits à finalité sanitaire et cosmétique destinés à l'homme)

[112] Circular No. DGS/PP2/2013/224 of 29 May 2013 on the application of Article 2 of Law No. 2011-2012 of 29 December 2011 relating to the enhancing of health safety of medicinal drugs and health products (Circulaire N° DGS/PP2/2013/224 du 29 mai 2013 relative à l'application de l'article 2 de la loi n°2011-2012 du 29 décembre 2011 relative au renforcement de la sécurité sanitaire du médicament et des produits de santé)

[113] French Ministry of Social Affairs & Health, Base Transparence Santé, available at https://www.transparence.sante.gouv.fr/ (last visited 29 September 2017)

[114] Point C.2.a of Circular No. DGS/PP2/2013/224, of 29 May 2013

[115] Decision of the French Supreme Administrative Court (Conseil d'Etat) N° 369074, of 24-02-2015. Décision nos 369074 et autres du 24 février 2015 du Conseil d'Etat

[116] This would typically apply to indirect sponsorship. The grant given to a PCO/HCO for indirect sponsorship will give rise to the publication of: information relating to the grant agreement itself (names of the parties, date of signature, total amount, etc.), including the names of the HCPs, who indirectly benefited from such grant as well as the nature and the value of such indirect benefit, and, separately the amount of the grant as an advantage.

IN VITRO DIAGNOSTICS: SIDIV

Updated: 22 September 2017

General update on the national code

The SIDIV[117] Ethics and Professional Deontology Charter ("SDIV Code") (*Charte Ethique et Déontologie Professionnelle*)[118], was approved on 4 June 2014. SDIV is in ongoing discussions with regard to transposition plans for the MTE Code.

Procedural highlights

SDIV created the 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[119]. SDIV does not have its own Competition Law Guidelines.

Financial support of HCPs for attendance at Third Party Organised Educational Conferences

The SIDIV Code of Ethics does not impose specific limits regarding sponsorship, consultancy agreements, hospitality or gifts, but the French Code of Public Health, among other regulations, is also applicable to the IVD sector. As a consequence, the prior opinion procedure and the notification obligation introduced by the Bertrand Law, both described in the medical devices chapter above, are also applicable for IVD companies[120]. For the avoidance of doubt, IVD companies will have to report their activities and obtain a prior opinion from their competent professional board (either from the the *Conseil National de l'Ordre des Médecins*, or from the *Conseil National de l'Ordre des Pharmaciens*).

Arrangements with consultants

As in the case of medical devices companies, the prior opinion required by the French Code of Public Health before implementing a consultancy agreement is also required in the IVD sector. Please, refer to the "Arrangements with consultants" section of the SNITEM chapter above for more information.

Meals, travel and accommodation expenses

As in the case of previous sections, the prior opinion required by the French Code of Public Health before granting any kind of hospitality is also required in the IVD sector, with the exception mentioned in the SNITEM section. Please refer to the "Meals, travel and accommodation expenses" section above.

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[117] SIDIV is the French industry association for the In Vitro Diagnostics industry: http://www.sidiv.fr/
[118] SIDIV Ethics and Professional Deontology Charter (SIDIV Ethical Charter) (Charte éthique et déontologie professionnelle), adopted on June 2014 (There is no English version available).
[119] Arts 14-15, Section IV, SIDIV Ethical Charter, June 2014
[120] See SNITEM section for further information

Gifts

Please, refer to the SNITEM section on gifts for information on the prohibition of gifts as regulated in the French Code of Public Health, as it also affects the IVD sector.

Transparency

The modifications introduced by the Bertrand Law, including the disclosure obligation, also apply to IVD companies. Therefore, please refer to the “transparency” section of the SNITEM chapter for more information.

GERMANY

MEDICAL DEVICES: BVMED & SPECTARIS

Updated: 21 September 2017[121]

General update on the national codes

Two German medical devices associations are members of MedTech Europe.

BVMED

The latest version of BVMed's Device Code of Ethics ("BVMed Code")[122] (Kodex Medizinprodukte) and was approved by the board in September 2016. In addition, BVMed is also a party to the "Common Position" (Gemeinsamer Standpunkt), which was signed among different stakeholders in the healthcare field in 2000. BVMED has no current plans for transposition of the MTE Code.

SPECTARIS

SPECTARIS published its Code of Conduct (SPECTARIS Code)[123], (Empfehlungen zur Zusammenarbeit in der Gesundheitswirtschaft) in 2011. However, on 28 September 2017 SPECTARIS' Medtech members voted and approved a new SPECTARIS Code of Conduct. This new Code transposes the MTE Code, with the exception of part 3-Procedural Framework. Additionally, it is important to note that SPECTARIS' new Code is meant to provide guidance and recommended best-practices to its members. The new Code comes into force on 1 January 2018.

Procedural highlights

BVMED

The BVMed Code does not have a formal enforcement mechanism. However, mediations are conducted by the Healthcare Compliance Committee, which is composed of association members. The Committee was created in 2009. Additionally, BVMed does not have Competition Law guidelines, although its Code is partially based on the Act against unfair competition[124].

SPECTARIS

SPECTARIS' current Code does not contain a formal enforcement mechanism. Moreover, its new Code also does not include enforcement or sanction mechanisms. In addition, it does not have its own Competition Law guidelines.

[121] This section was not reviewed by BVMed, an update regarding Code transposition is due late October.
[122] Kodex Medizinprodukte (BVMed Code), BVMed, September 2016. There is no English version available.
[123] Code of Conduct, Recommendation on relations with Healthcare Professionals (Empfehlungen zur Zusammenarbeit in der Gesundheitswirtschaft), 2011. There is no English version available.
[124] Preamble, p 2, BVMed Code

Financial support of HCPs for attendance at Third Party Organised Educational Conferences

There are no legal authorisation/notification requirements that apply. However, they are imposed indirectly through existing laws and codes of conduct. Companies should abide by certain practices when sponsoring public HCPs to attend Third Party Organised Educational Conferences in order to avoid potential allegations of corruption. Based on such practices, prior to any sponsorship of public HCPs, the company should ensure that HCPs have obtained the approval of their supervisor/administration of the employing hospital ("Employer's Approval"'). The company may reimburse costs only if it has received the Administrator's Consent in writing. In addition, companies are only allowed to cover registration, travel and accommodation costs, excluding additional meals not covered by the accommodation or registration fees. These guidelines derive from the German Criminal Code[125] and other regulations described by the BVMed Code[126].

The latest update of the BVMed Code entered into force in January 2015, and it expanded the scope and some definitions of the Code[127]. The definition of HCP was also broadened. Previous versions of the Code made no difference between public, private or non-profit hospitals, and this consideration has been extended to private physicians and their staff. These changes match the new German legislation that entered into force in June 2016[128]. The core part of these rules is the introduction of corruption in the healthcare sector as a statutory offense. This complements and partially modifies the existing rules on anti-bribery in Germany.

At national level, there are talks of a revision of the medical professional code by the German Medical Association (Muster-Berufsordnung der Bundesaerztekammer [MBO])[129] which would take place in 2018 at the earliest.

Arrangements with consultants

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[130].

Meals, travel and accommodation expenses

The BVMed Code and the Common Position do not provide guidance on the maximum amount for meals, travels and lodging. According to these guidelines, registration fees, meals, travel and lodging expenses should be reasonable in value and directly related to the event. Based on case law, BVMed periodically develops opinions or recommendations on interpretation of its Code[131]. One such recommendation focused on the interpretation of hospitality[132]. According to this recommendation,

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[125] Sections 299, 331, 332 and 333, 334, Criminal Code (Strafgesetzbuch, StGB)
[126] Art. 2 and 8, the German Medical technology Association – BVMed – Medical Device Code of Ethics (BVMed Kodex Medizinprodukte), January 2015
[127] Art. 1 & 3 of the BVMed Code.
[128] Sections 299 a, 299 b StGB Criminal Code Strafgesetzbuch, StGB)
[129] To find in its current version on www.bundesaerztekammer.de , subsection "Recht"
[130] Art. 8, BVMed Code
[131] These opinions are issued by the BVMed Healthcare Compliance Committee, which was established in 2009 in order to support BVMed in all ethics related issues
[132] BVMed Recommendation published at the MedTech Kompass newsletter, May, 2011: http://www.medtech-kompass.de/depesche-detailansicht/items/depesche-nr-13.html (last accessed 28 September, 2017)

working lunches are generally permitted; however, they have to be properly documented[133]. It is only allowed to cover meal costs for internal education events of member companies and working lunches. Working lunches are not allowed in connection with the sales of products or the creation of business opportunities. Based on other existing practices[134], meals ranging between EUR 50 to 60 should be generally acceptable. In exceptional situations higher costs might be appropriate if duly justified[135].

Gifts

Although gifts are generally not allowed, there are some exceptions to the rule[136]:

- Advertising gifts of minor value.

[133] BVMed recommendation.
[134] For example the ones applied by the German Medical Association (Bundesärztekammer)
[135] BVMed recommendation
[136] Art. 11, BVMed Code

IN VITRO DIAGNOSTICS: VDGH

Updated: 13 September 2017

General update on the national code

The VDGH[137] Code of Ethics [138] ("VDGH Code")(*Kodex für die Mitglieder des VDGH*), was last amended on 3 January 2013, and published on 22 January 2013. VDGH is also a party to the "Common Position" (Gemeinsamer Standpunkt) which was signed among different stakeholders in the healthcare field in 2000.

As VDGH's Code does not apply to all of its members, there is no current plan for transposition of the MTE Code, insofar as its goes beyond German Law. However, VDGH recognizes that the MTE Code is the European industry standard and supports its aims. To that end, it has created and dispensed material explaining the MTE Code, its obligations, and the timeline for the transition periods, in order to ensure all its members are accurately informed.

Procedural highlights

VDGH does have an enforcement mechanism, though it is supervised by FSA e.V. (Free Self-Control of Pharmaceutical Industry), an association which was created to implement the Code of Ethics of the German pharmaceutical industry, and not its own arbitrative board. Moreover, the right of companies to file complaints is restricted to breaches of the provisions of Article 4 of the FSA Code Healthcare Professionals.

The complaints are submitted to the Code of Procedure for Arbitration of the FSA. Two chambers (First and Second Instance) are created, where the IVD industry is represented. The Chamber of First Instance has responsibility at first instance for all complaints for which the Chamber of Second Instance does not have jurisdiction. If a complaint is admissible and well-founded, the Chamber of First Instance must demand a declaration of discontinuance protected by criminal sanction. If the member refuses to give such a declaration of discontinuance, then the proceedings are continued before the Chamber of First Instance. If the complaint proves to be admissible and well-founded during these proceedings, then the Chamber of First Instance issues a finding that there has been a breach of the Code. VDGH does not provide separate Competition Law guidelines, although its Code is partially based on the Act against unfair competition, Act on advertising in the field of medicine and Act of penalty.

Financial Support of HCPs for attendance at Third Party Organised Educational Conferences

According to the VDGH Code[139], where permitted under national and local laws, regulations and professional codes of conduct, members may provide financial support to cover the cost of

[137] VDGH is the German association representing the German IVD Diagnostics http://www.vdgh.de/
[138] No English version available. It is important to highlight that the VDGH Code only applies to its self-testing IVD members (e.g. manufacturers of blood glucose strips)
[139] VDGH Code of Ethics (VDGH Code) (Kodex für die Mitglieder des VDGH, die IVD-Medizinprodukte nach § 3 Nr. 5 MP
G herstellen, die auch zur Eigenanwendung bestimmt sind (Eigenanwendungs-IVD), first edition from 2008, last amended in January 2013. See section 20 for the provisions on support for medical education.

conference attendance by individual HCPs. Such financial support should be limited to the conference registration fee and reasonable travel, meals and accommodation costs relating to attendance at the event. As in the case of Medical Devices, there are no legal authorisation or notification requirements that apply, but VDGH is also a party to the "Common Position of the Associations for assessing the Collaboration between Industry, Medical Facilities and their Employees in Reference to German Criminal Law", and therefore IVD Companies should make sure that prior approvals from the HCP superior have been obtained.

Arrangements with consultants

The VDGH Code allows for member companies to enter in consultancy agreements with HCPs subject to certain conditions, namely, the existence of a written agreement clearly stating the scope and financial aspects of the agreement[140]. Reasonable expenses may also be covered. As with the sponsorship for attendance to Third Party Organised Educational Conferences, this relationship needs to be reported to the hospital or the public institution administration in writing by the HCP and prior approval from the HCP superior needs to be obtained.

Meals, travel and accommodation expenses

According to the VDGH Code, hospitality and accommodation must not exceed reasonable limits[141]. Travel costs may also be covered provided the training activity or the event of medical relevance remains the main attraction.

Gifts

Although gifts are generally not allowed, there are some exceptions to the rule[142]:

- Advertising gifts of minor value.

Transparency

Members bound by VDGH's Code, must publish all grants above 10.000 Euro on the member's homepage[143].

[140] Art. 18.3, VDGH Code.
[141] Art. 20.3, VDGH Code.
[142] Common Position, Art. 21, VDGH Code
[143] Art. 25(4), VDGH Code

GREECE

MEDICAL DEVICES& IN VITRO DIAGNOSTICS: SEIV

Updated: 5 October 2017[144]

General update on the national code

The SEIV[145] Code[146] (*ΣΕΙΒ Κώδικα Δεοντολογίας)* was last amended in March 2012. Further to this, SEIV adopted the Eucomed Guidelines on Interactions with Healthcare Professional in 2013. SEIV has drafted a new Code which brings it in line with the MTE Code. This new Code was approved on 22 June 2017 and goes into force 1 January 2018.

Procedural highlights

The SEIV Code is enforced with its complaint handling system, which was adopted in 2006. It is managed by the SEIV Executive Committee (SEIV Board of Directors). Disciplinary sanctions imposed by the Executive Committee may be appealed to the General Assembly.

Financial support of HCPs for attendance at Third Party Organised Educational Conferences

According to the current SEIV Code, members are allowed to cover certain hosting expenses of HCPs who participate at Third Party Organized Educational Events, such as, for example, scientific societies. In particular, only the following expenses may be covered: registration fees, accommodation, meals and travel costs. These expenses must be reasonable and fully related to the purpose of the event[147]. In addition, the National Medicines Organization (hereinafter referred to as "EOF") needs to approve in advance the sponsorship of HCPs related to the European and rest of the world events. Although prior approval is not required when it comes to sponsorship related to the local events, a detailed report, including actual expenses, after such events needs to be submitted to EOF. Moreover, it is important to note that publicly employed HCPs are not allowed to attend company promotional meetings[148].

EOF has issued several rather detailed circulars applicable to sponsorship and organisation of scientific events. For more information refer to EOF website[149].

Arrangements with consultants

Currently, SEIV applies the same rules as Eucomed[150]. According to the current SEIV Guidelines[151], where no national requirement is prescribed, members shall maintain appropriate transparency by

[144] This section has not been reviewed by the national association
[145] SEIV is the Greek Medical Devices Association, previously known as HELLASMES: http://www.seiv.gr/
[146] There is no English version available.
[147] Art. 7, SEIV Members' Code of Ethics (SEIV Code) (ΚΩΔΙΚΑΣΔΕΟΝΤΟΛΟΓΙΑΣΜΕΛΩΝ), March 2012
[148] This is explicitly forbidden by EOF and, as a result, by the SEIV Code (see art. 7.6)
[149] http://www.eof.gr
[150] On 17 April 2013 SEIV adopted the Eucomed Guidelines on Interactions with HCPs which were translated in Greek.

requiring 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. Moreover, consulting agreements should comply with the criteria laid down in Section V of the SEIV Guidelines including, for example[152]:

- Consulting agreements should be entered with a legitimate purpose identified in advance,
- Consulting agreements should be made in writing, in accordance with local and national law and should fully disclose the purpose and the scope of the agreement,
- The compensation of the HCP should be fair market value for the services provided and should not be tied in any way to the value of medical technology products which the consultants may use for their own practice etc.

Meals, travel and accommodation expenses

According to EOF Circulars related to scientific events in Greece, lodging expenses for local events cannot exceed EUR 140 per day per HCP (including VAT), while for European and rest of the world events these expenses are limited to 280 EUR per day per HCP (excluding VAT)[153]. Expenses for meals cannot go beyond EUR 70[154]per day per HCP regardless of where the event is held[155,]

The article 7.7 of the SEIV Code allows covering reasonable hospitality and travel costs. More precisely, companies can cover costs of meals and accommodation as well as travel expenses from the HCPs' establishment to the event's place. In addition, these expenses must be reasonable and fully related to the purpose of the event[156]. Similar rules are provided in the SEIV Guidelines[157].

Gifts

Generally, the Greek legislation does not permit gifts unless they are of negligible value and related to the HCPs' practice[158]. According to the SEIV Guidelines, members occasionally may 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 practise. Gifts must relate to the HPC's practice, benefit patients or serve a genuine educational function. Gifts must not be given in the form of cash or cash equivalents[159, 160].

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[151] SEIV Guidelines on Interactions with HCPs (SEIV Guidelines) (ΚατευθυντήριεςγραμμέςτουΣΕΠσχετικάμεσυναλλαγέςμεεπαγγελματίεςυγείας), 17 April 2013. SEIV Guidelines is a translation of Eucomed Guidelines.
[152] See Section V for all criteria, SEIV Guidelines
[153] Stricter rules may apply under the laws of different countries and/or each company's compliance guidelines.
[154] For local events amount includes VAT, while for European and rest of the world ones VAT is excluded.
[155] EOF circular for scientific events No. 64740 of 06.09.2013
[156] Art. 7.7, SEIV Code
[157] Section II, Section III and Section IV, SEIV Guidelines
[158] Art. 114, p. 1, Joint Ministerial Decision DYG3(a)/83657 (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
[159] Section VI, SEIV Guidelines
[160] Stricter rules may apply under the laws of different countries and/or each company's compliance guidelines.

HUNGARY

MEDICAL DEVICES: AMDM

Updated: 11 September 2017

General update on the national code:

The AMDM Code of Ethics ("AMDM Code") (AMDM Etikai kódex) was approved on 23 March 2011. The Code is also translated into English. AMDM is currently promoting the use of the MTE Code as a best practice to its members. More details to follow.

Procedural highlights

AMDM enforces its Code through the Ethics Committee, which was created in 2005. This committee is composed of association members and the association's Director General[161]. AMDM does not currently provide Competition Law guidelines.

Financial support of HCPs for attendance at Third Party Organised Educational Conferences

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"[162].

Companies may also provide support for events and programs for purely professional and scientific purposes. Such support must be reasonable in scope as well as subordinate to the main scientific objective of the meeting[163].

Arrangements with consultants

There are no specific rules or guidance currently included in the AMDM Code pertaining to consultants.

Meals, travel and accommodation expenses

See above "Financial support of HCP for attendance at Third Party Organised Educational Conferences".

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[161] Art. 5, p 3, AMDM Code of Conduct (English version); Section 5, Art. 6.1, p. 15, Az Orvostechnikai Eszközök Gyártóinak és Forgalmazóinak Szövetsége (Orvostechnikai Szövetség)
ALAPSZABÁLYA (Statutes-Association of Medical Device Manufacturers and Distributors), 7 May 2015 (last visited 11 September 2017)

[162] Art. 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 (2006. évi XCVIII. Törvény a biztonságos és gazdaságos gyógyszer- és gyógyászatisegédeszköz-ellátás, valamint a gyógyszerforgalmazás általános szabályairól)

[163] Art. 14, p 3, Act XCVIII of 2006

In addition, 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[164].

Gifts

According to the Act XCVIII of 2006, gifts are not allowed unless they are inexpensive and related to the professional activity of the HCP[165]. *Inexpensive* means that the value of the gift does not exceed 5% of the official minimum wage[166]. Additionally, the total value of the gifts on an annual basis cannot exceed 60% of the official minimum wage[167]. Furthermore, gifts in the form of cash or cash equivalents are prohibited[168].

Transparency

The transparency obligations laid down in Act XCVIII of 2006 applies not only to the pharma industry, but also to companies producing medical aids[169]. 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.

[164] Art. 14, p. 2, Act XCVIII of 2006
[165] Art. 14, p. 1, Act XCVIII of 2006
[166] Art. 3, p. 8, Act XCVIII of 2006. Minimum wage for 2017: HUF 127.500 (approx. EUR 412).
[167] Art. 14, Act XCVIII of 2006
[168] Art. 14, p. 1, Act XCVIII of 2006
[169] 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

IN VITRO DIAGNOSTICS: HIVDA

Updated: 6 October 2017

General update on the national code

HIVDA's[170] Code of Ethics[171] ("HIVDA Code") (HIVDA Etikai Kodex), entered into force in January 2006. However, in 2017 HIVDA adopted the MTE Code and translated it into Hungarian[172]. The new HIVDA Code will come into force on 1 January 2019 and HIVDA is recommending it as best practice to all its member companies.

- Nevertheless, until 31 December 2018, the current HIVDA Code remains in force.

Procedural highlights

Under its current Code, complaints are directed to the President of HIVDA, who decides whether it is necessary to convene an ad-hoc Ethics Committee to assess the issue. HIVDA"s new Code does not contain Competition Law guidelines.

Financial support of HCPs for attendance at Third Party Organised Educational Conferences

This is regulated by a Hungarian Law and not by an association code of practice. Please refer to the "Sponsorship of HCPs for attendance at Third Party Organised Educational Conferences" section of the Medical Devices chapter on Hungary for the legal overview of the situation.

Arrangements with consultants

The HIVDA Code[173] provides that agreements with consultants must be in writing and signed by the parties, as well as all the services to be provided must be clearly defined. Such agreements must be in accordance with other statutory provisions. HCP's remuneration should be based on the nature of the service actually provided, and needs to be proportionate and compliant with any other legal requirements. Members may cover reasonable expenses that may arise in the course of the service[174]. Once the new HIVDA Code comes into force please refer to the MTE Code section on Arrangements with Consultants [175]

Meals, travel and accommodation expenses

This is regulated by a Hungarian Law and not by an association code of practice. Please refer to the "Meals, travel and accommodation expenses" section of the medical devices chapter on Hungary for

[170] The Hungarian Diagnostics Association: http://www.hivda.hu/english
[171] There is no English version available.
[172] MedTEch Europe Az üzleti gyakorlat etikai kódex (MedTech Europe Code of Ethical Business Practice)
[173] HIVDA Code of Ethics (Etikai Kódex), January 2006.
[174] HIVDA Code, Section IV, January 2006
[175] Part 1 Ch. 5 – Arrangements with Consultants, MTE Code

the legal overview of the situation. Once the new HIVDA Code comes into force Please refer to the MTE Code section on General Criteria for Events[176].

Gifts

This is currently regulated by a Hungarian Law and not by an association code of practice. Please refer to the “Gifts” section of the Medical Devices chapter on Hungary for the legal overview of the situation.

Transparency

Please see the section about medical devices for more information.

[176] Part 1 Ch. 1 – General Criteria for Events, MTE Code

IRELAND

MEDICAL DEVICES & IN VITRO DIAGNOSTICS: THE IRISH MEDTECH ASSOCIATION & IMSTA

Updated: 3 October 2017[177]

MedTech Europe has two Irish national Association members.

IRISH MEDTECH

General update on the national code:

The Irish Medtech Association ("Irish Medtech")[178], previously known as IMDA, approved its current version of the Code of Ethical Business Practice in 2011. However, Irish Medtech has transposed and adopted the MTE Code as its new Code, which will enter into force in line with the MedTech Europe Code in 1st January 2018

Procedural highlights

Irish Medtech currently enforces its Code through a complaints procedure and Panel Constitution[179]. 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.

Financial support of HCPs for attendance at Third Party Organised Educational Conferences

As mentioned above, under Irish Medtech's new Code the ban on direct sponsorship does not come into force until 1 January 2018. As a result, until that date—where permitted under local laws, regulations and professional codes of conduct—direct sponsorship of HCPs is still deemed appropriate and thus, must follow the requirements specified in the Irish MedTech Code.

From 1 January 2018 on, direct sponsorship will be prohibited and Educational Grants become the only way to provide financial support to healthcare professionals to attend Third Party Organised Educational Conferences. As always, conferences benefitting from an Educational Grant still need to comply with all the specific requirements as set out in the Code[180].

Arrangements with consultants

Please refer to the MTE Code section on Arrangements with Consultants[181].

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[177] This section has not been reviewed by the national association
[178] The Irish Medtech Association: http://www.irishmedtechassoc.ie/
[179] Complaint Procedure & Panel Constitution, Irish Medtech Association, revised December 2014 (last visited 6 October 2017)
[180] MTE Code Chapter 1: General Criteria for Events
[181] Part 1 Ch. 5 – Arrangements with Consultants, MTE Code

Meals, travel and accommodation expenses

Please refer to the MTE Code section on General Criteria for Events[182].

Gifts

Please refer to the MTE Code section on Educational Items and Gifts[183].

Transparency

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

[182] Part 1 Ch. 1 – General Criteria for Events, MTE Code
[183] Part 1 Ch. 8 – Educational Items & Gifts, MTE Code

IMSTA

General update on the national code:

The Irish medical technology supply industry's (IMSTA) current Code is Eucomed's Code of Ethical Business Practice. However, in 2016 IMSTA approved the new MTE Code. The new IMSTA Code comes into force on 1 January 2018. The new IMSTA Code is an exact transposition of the MTE Code.

Procedural highlights

IMSTA's current enforcement mechanism will continue for its new Code. This grievance procedure is run by the Ethics and Compliance Group and any hearings are headed by independent chairpersons. Initial findings of the Ethics and Compliance Group may be appealed and any further finding will be referred to IMSTA's Board to decide what action if any should be taken.

Financial support of HCPs for attendance at Third Party Organised Educational Conferences

Please refer to the MTE Code section on Third Party Organised Educational Events[184].

Arrangements with consultants

Please refer to the MTE Code section on Arrangements with Consultants[185].

Meals, travel and accommodation expenses

Please refer to the MTE Code section on General Criteria for Events[186].

Gifts

Please refer to the MTE Code section on Educational Items and Gifts[187].

[184] Part 1 Ch. 2 – Third Party Organised Educational Events
[185] Part 1 Ch. 5 – Arrangements with Consultants, MTE Code
[186] Part 1 Ch. 1 – General Criteria for Events, MTE Code
[187] Part 1 Ch. 8 – Educational Items & Gifts, MTE Code

ITALY

MEDICAL DEVICES & IN VITRO DIAGNOSTICS: ASSOBIOMEDICA

Updated: 11 September 2017

General update on the national code

The latest version of the Assobiomedica's[188] Code of Ethics ("Assobiomedica Code") (Codice Etico) was published in June 2015. The English version of the Code is also available on the association's website. In addition, Assobiomedica enters into yearly agreements with several hotel associations (Verbali). The latest one was signed in September 2016. Assobiomedica is currently in discussions on transposing the MTE Code and plans to hold an event for stakeholders in the fall to discuss the prohibition on direct sponsorship. The goal of Assobiomedica is to support the members that are applying the MTE Code to promote knowledge of the application of the new sponsorship methods. However, there is still an internal discussion within the association on the adoption of the MedTech Code for all associates.

Procedural highlights

In 2010, Assobiomedica created the Control Commission and Jury. This Commission and Jury handle enforcement of the Assobiomedica Code[189]. In addition, Assobiomedica has an Antitrust Handbook and Competition Law Guidelines[190].

Financial support of HCPs for attendance at Third Party Organised Educational Conferences

Assobiomedica member companies may offer financial assistance to cover the conference attendance costs as well as the reasonable travel and lodging expenses borne by HCPs at third party scientific events[191]. In addition, according to the Assobiomedica's Code, a prior communication/authorisation is required when sponsoring HCPs' attendance at such scientific conferences. This requirement derives from a more general prior-authorisation obligation applicable to public service employees in Italy[192]. A two-fold requirement is laid down in the Code[193]:

- When sponsoring HCPs to passively attend Third Party Organised Educational Conferences: A member company concerned has to send a communication to a relevant public administration (i.e. HCPs' employer). In the communication, a member company may suggest one or more names of potential attendees whose expertise is related to the topic of the event. However, only a public administration is allowed to decide what HCPs will attend. If a public administration does

[188] Assobiomedica is the Italian Association representing companies manufacturing biomedical products and technologies in the healthcare sector: http://www.assobiomedica.it/it/index.html
[189] Art. 4, Assobiomedica Code of Ethics (Assobiomedica Codice Etico); December 2014
[190] Linee Guida in Materia Antitrust & Manuale Antitrust, Assobiomedica, Linee Guida, available at https://www.assobiomedica.it/it/analisi-documenti/linee-guida/index.html# (last visited 12 September 2017)
[191] Art. 2.7.2, Code of Ethics
[192] Art. 53, Legislative Decree 165/2001 laying down the general rules applicable to employment in public administration (Legislative Decree 165/2011) (Decreto Legislativo 165/2011 "Norme generali sull'ordinamento del lavoro alle dipendenze delle amministrazioni pubbliche")
[193] Art. 2.7, Code of Ethics

not respond or authorises the sponsorship, a member company may provide a financial support directly to the congress organiser.

- When sponsoring HCPs who receive remuneration (e.g. speakers at the conference): The process is the same as above, however, a sponsoring member company must obtain an explicit authorisation by a public administration to provide a financial support.

Under the Assobiomedica Code[194], it is forbidden to sponsor HCPs to attend events in seaside resorts from June 15 to September 30 and in mountain resorts from June 15 to September 30 and from December 15 to March 30.

Arrangements with consultants

The Assobiomedica 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[195]:

- 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 HCP is professionally active
- A 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 Assobiomedica 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[196].

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 therefore would be forbidden[197]. Consultancy services 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.

[194] Art. 2.7.2, p 14, Code of Ethics
[195] Art. 2.10, Code of Ethics (see the article for all requirements)
[196] 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
[197] General Requirements for Engagements Prohibited to Public Service Employees (Criteri generali in materia di incarichi vietati ai dipendenti delle amministrazioni pubbliche), August 2014

Meals, travel and accommodation expenses

As specified above, member companies may cover conference attendance costs as well as the reasonable travel and lodging expenses borne by HCPs at third party scientific events[198]. Hospitality and travel expenses have to be limited to the duration of the scientific event and cannot exceed 24 hours before or after the event[199]. In addition, any hospitality must be related to the scientific objective of the event. According to the Assobiomedica Code, hotel rating cannot be higher than four-stars, except for hotels and conference venues that have adhered to the agreements signed between Assobiomedica and several Italian Associations of Hotels[200]. 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[201].

Gifts

Generally the gifts are not allowed unless they are of low value[202].

Transparency

There are transparency rules 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)[203]. These transparency provisions were amended by the new Anti-Corruption Law. In particular, the reporting periods were changed: instead of once per year, the companies now have to report no later than 15 days after the payment[204].

The services excluded[205] 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
- 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

This requirement is included in the Assobiomedica Code[206].

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[198] Art. 2.7.2, Code of Ethics
[199] Art. 2.7, Code of Ethics
[200] 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 Assobiomedica Code. These were included in the last revision of the Code (December 2014).
[201] Art. 2.7.2, Code of Ethics
[202] Art. 2.7, Code of Ethics
[203] Legislative Decree 165/2001 of 30th March, Article 53
[204] Law no 190/2012 of 6th November, Article 1, paragraph 42.
[205] Legislative Decree 156/2001 Article 53, paragraph 6.
[206] Art. 2.10, Assobiomedica Code of Ethics

MIDDLE EAST

MEDICAL DEVICES: MECOMED

Updated: 26 September 2017

General Update on the national code

The current Mecomed[207] Code of Business Practice ("Mecomed Code") was amended in 2015. Please find it here. However, Mecomed revised its Code this year—finally approving it on 18 June[208]—which brings it in line with the MTE Code. It should be noted that Mecomed's new Code applies to all Mecomed member companies as well as to all Third Party Intermediaries[209].

The new Mecomed Code will come into force as follows:

- 1 January 2018 the entirety of the Code with the exception of part 2 will enter into force.
- 1 January 2019 the disclosure guidelines (Part 2) will enter into force.

- Therefore, until 1 January 2018, the current Mecomed Code remains in force.

Procedural highlights

Mecomed's current Code is enforced through its Internal Escalation Procedure, and its new Code will also be enforced with the same process[210], which continues under the new Code. The body in charge of coordinating the resolution of conflicts is the Escalation Committee. It is formed by the head of the MECOMED Compliance Steering Group and two compliance officers who have at least 2 years of experience in compliance roles and regularly attend MECOMED face to face meetings[211].

Financial support of HCPs for attendance at Third Party Organised Educational Conferences

Until 31 December 2017 and under the current Mecomed Code, where it is permitted under national and local laws, regulations and professional codes of conduct, members may provide financial support to cover the cost of conference attendance by individual HCPs. Such financial support should be limited to the conference registration fee and reasonable travel, meals and accommodation costs relating to attendance at the event. Members must ensure full compliance with national and local laws with regard to the disclosure or approval requirements associated with such sponsorship and where no such requirements are prescribed, shall nevertheless maintain appropriate transparency, for

[207] Mecomed is the association of Medical Device and Equipment companies operating in the Middle East: http://www.mecomed.com
[208] Code of Ethical Business Practice : Mecomed Guideliens on Interactions with HCPs & HCOs (Mecomed Code), May 2017
[209] Part 3: Procedural Framework, p 28, Mecomed Code, May 2017
[210] Part 3: Procedural Framework, p 28 & 29, Mecomd Code, May 2017
[211] Part 6 : Glossary and Definitions, p 37, Mecomed Code, May 2017

example, by requiring prior written notification of the sponsorship is made to the hospital administration, the HCP's superior or other locally-designated competent authority[212].

Please, note that 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 www.ethicalmedtech.com.

As of 1 January 2018, Mecomed's new 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 new 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.

Mecomed's new Code also formalises the extension of the Conference Vetting System (CVS) to national Third Party Organised Educational Events taking place in Mecomed geographic scope.

Arrangements with consultants

The new Mecomed Code maintains the same requirement as the current Code, which 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 new Mecomed Code[217]:

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

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].

[212] Section III, Mecomed Code of Business Practice: Guidelines on Interactions with Healthcare Professionals (Mecomed Code), 2015
[213] Part 3: Procedural Framework, p 28, Mecomed Code, May 2017
[214] Part 1: Guidelines on Interactions with HCPs and HCOs, p 11, 14-15, Mecomed Code, May 2017
[215] Part 1: Guidelines on Interactions with HCPs and HCOs p 16, Mecomed Code, May 2017
[216] Part 1: Guidelines on Interactions with HCPs and HCOs, p 11, Mecomed Code, May 2017
[217] For the rest of the requirements see Part 5.2: Section V, Mecomed Code, May 2017
[218] Section III, Mecomed Code, 2015; Part 1 : Guidelines on Interactions with HCPs and HCOs, p 10-11, Mecomed Code, May 2017

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 longer than 5 hours unless special health conditions make traveling in business class necessary, in which case an exception may be granted.

Mecomed's new Code kept guidance on how to proceed in situations where female HCPs are required to be accompanied by their spouse, a male family member, or other eligible person when traveling to attend member-sponsored trainings and/or third party events. Mecomed members may facilitate these travel arrangements, but the costs must be covered by the HCP herself[219].

Gifts

The new Mecomed Code has the same principles as the MTE Code, but provides more details on what are appropriate gifts. In particular, generally gifts should be of benefit for the patient provided they are of modest and reasonable value unless it is a text book or a medical journal subscription when USD 500 (around EUR 392) per HCP/year is allowed. Neither cultural gifts nor gifts or flowers for major life events (e.g. wedding) are allowed.

Transparency

Under Mecomed's new Code, member companies must document and disclose all Educational Grants according to its Disclosure Guidelines[220]. The Disclosure Guidelines will come into force only on 1 January 2019. Therefore, publication of Educational Grants must begin no later than the end of the transition period: 1 January 2019[221].

Misc.

One of the most notable differences between Mecomed's new Code and the MTE Code is its scope, which unlike the MTE Code also includes Third Party Intermediaries[222]. Mecomed's new Code will require 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.

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[219] Addendum I, Mecomed Code, 2015 ; Part 1 : Guidelines on Interactions with HCPs and HCOs, p 9, Mecomed Code, May 2017
[220] Part 1 : Guidelines on Interactions with HCPs and HCOs, p 17, Mecomed Code, May 2017
[221] Part 6 : Glossary and Definitions, p 40, Mecomed Code, May 2017 (The transition period runs from June 2018-1 January 2019)
[222] Part 4 : Third Party Intermediaries Compliance & Due Diligence, p 30, Mecomed Code, May 2017

THE NETHERLANDS

MEDICAL DEVICES: NEFEMED & FHI

General update on the national code

The Dutch Code of Conduct (Gedragscode Medische Hulpmiddelen ("GMH Code")) is an industry wide Code. In 2011 six Dutch industry associations (Diagned, FHI, Firevaned, GAIN, Holland HealthTech and Nefemed) reached an agreement on the Dutch Code. More healthcare stakeholders subscribed to the Dutch Code in the following years, for example, hospitals', doctors' as well as dental medical device associations. There is also an English version available. The Code was amended in 2015. Discussion on revising the GMH Code is underway, in order to bring it in line with new Dutch legislation and the MTE Code. The GMH Board hopes to implement the ban on direct sponsorship by summer 2018. Further plans for transposition will also be discussed. Decisions are expected in 2018.

Procedural highlights

Compliance with the GMH Code is enforced with an industry wide mechanism, composed of a Code Committee and Appeals Board (external stakeholders)[223]. The GMH Code does not include Competition Law guidelines.

Financial support of HCPs for attendance at Third Party Organised Educational Conferences

According to the GMH Code, the sponsorship of HCPs to attend Third Party Organised Educational Conferences is allowed, if it is in accordance with the requirements laid down in the article 9.2 of the Code. Companies may cover reasonable expenses incurred by individual HCPs (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[224]. In addition, HCP must notify arrangements concerning the reimbursement of expenses to the board of the institution or his/her employer[225].

However, please note that in May 2017 amendments were made to the Dutch Act on Medical Devices, which regulate the offering and acceptance of business gifts in relation to medical devices[226]. These amendments will enter into force on 1 January 2018[227]. This amendment prohibits companies from offering business gifts to HCPs, both in the form of money, as well as any other business item that has monetary value. It does however provide limited exceptions to this prohibition, which include support for educational meetings and products demonstrations, and product trainings.

[223] Monitoring, p 3, GMH Code of Conduct Medical Devices (GMH Code) (Gedragscode Medische hulpmiddelen), 2015
[224] Art. 9, p 2, GMH Code
[225] Art. 9, p 3, GMH Code
[226] Act of 17 May 2017, Official Gazette of the Kingdom of the Netherlands (Wet van 17 mei 2017, Staatsblad van het Koninkrijk der Nederlanden)
[227] Decision of 3 July 2017, Official Gazette of the Kingdom of the Netherlands (Besluit van 3 juli 2017, Staatsblad van het Koninkrijk der Nederlanden)

Arrangements with consultants

Arrangements with consultants are allowed if in compliance with the criteria specified in Articles 13 and 14[228]:

- Legitimate objective of the service
- Choice of service provider is based on his/her qualifications and expertise
- Written agreement of a limited duration[229]
- 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 Code introduced a definition of what "in line with the market" mean regarding consultancy hourly fees to be paid to different types of HCPs[230]. These amounts are:

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

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[231]. It is important to note that for some categories of the meetings it is clarified what *reasonable* means[232]. For example, see above the rules applying to the Third Party Organised Educational Conferences.

The 2015 revision of the Code has, however, 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
- Aeroplane: first class not permitted, business class permitted for intercontinental flights

Gifts

Currently under the GMH Code, occasional gifts of little value (i.e. max € 50 including VAT) are allowed. Gifts should be related to business of the HCP, be of benefit to patient care or fulfil a purely

[228] See Articles 13 and 14 for all criteria
[229] Article 14 lays down the essential elements of the written agreement.
[230] Explanatory notes section, regarding Article 13, GMH Code.
[231] Articles 9(2c), 10(2c), 11(2c), 12(2c), GMH Code
[232] Meetings organized by independent third parties, art. 9 (2c), accredited meetings organized by suppliers, art. 11(2c), other meetings organized by suppliers, art. 12(2c), GMH Code

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[233].

As discussed above, the changes to the Dutch Act on Medical Devices prohibit companies from giving gifts and HCPs from accepting such gifts. However, one of the four exceptions is for business gifts of "nominal" value.

Transparency

In 2015 following the Dutch Ministry of Health's invitation to do so, the Dutch medical technology industry introduced a self-regulatory disclosure system similar to the one pharmaceutical companies have used in the Netherlands since 2013[234]. In April 2016 the data of 2015 was published by the following industry sectors covered by the pilot: ICDs, pacemakers, stents and hip and knee prostheses. The data of 2016 was published in April 2017. The register and the published data can be found on a web site called the "Transparency register care" (*Transparentieregister Zorg)*.[235]

On 1 January 2017, the pilot phase ended and the system was extended to the whole medical technology industry. The scope of the transparency system will be broadened to include all medical device industry specialists (except for GPs) and data will be published in April 2018.

The scope of the transparency system:

- Remuneration for consultancy services, sponsorship agreements, and agreements on fees for services between suppliers of medical devices and medical specialists other than educational events and clinical studies
- As of 2017, covers all medical specialists (except for GPs) entered in the BIG Register[236] (data to be reported in 2018)
- Only if the total annual amount per doctor is higher than EUR 500.

[233] Art. 7, GMH Code
[234] Articles 22 to 27 of the Code. Please, see also the Explanatory notes regarding these Articles.
[235] Please follow this link: http://www.transparantieregister.nl/en-GB/Home
[236] The BIG (Beroepen in de Individuele Gezondheidszorg) register is the official HCP register in the Netherlands

IN VITRO DIAGNOSTICS: DIAGNED

Updated: 21 September 2017

General update on the national code

Diagned[237], in addition to NEFEMED and FHI, the Dutch Medical Devices associations, is a party to the GMH Code. As a consequence, please refer to the chapter above.

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

NORWAY

MEDICAL DEVICES: MEDTEK NORGE

Updated: 3 October 2017

General update on the national code

The Medtek Norge[238], formerly known as LFH, has its Ethical Rules[239] ("Medtek Norge Code") *(Etisk regelverk for Medtek Norge)* that were approved and published in 2011. Further to this Medtek Norge also is party to agreements with the Norwegian Medical Association (2008) and with regional healthcare authorities (2014). As a result of Medtek Norge's regional agreements there are no current plans for transposition of the MTE Code as these agreements impose obligations equivalent to those of the Code.

Procedural highlights

Medtek Norge enforces its Code through the Ethics Council, which was created in 2001, and it is composed of association members and external stakeholders. The decisions of the Ethics Council can be appealed to the Assembly General. Medtek Norge does not have separate Competition Law guidelines

Financial support of HCPs for attendance at Third Party Organised Educational Conferences

Medtek Norge 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 is not allowed and 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[240].

Arrangements with consultants

A written agreement is required which describes the scope and objects as well as how the 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

[238] Medtek Norge (formerly known as LFH) is a professional organization representing the suppliers of technical medical equipment, medical disposables and devices and medical/technical aids in Norway: http://medteknorge.no/
[239] There is no English version of this document.
[240] Medtek Norge publication "Clear rules for interaction": http://medteknorge.no/samhandlingsavtaler/clear-rules-for-interaction/ [Accessed: 06 November 2016] based on Agreements with regional health authorities and the LFH (Norwegian Association of Medical Suppliers) regarding the interactions between HCPs (Agreements with Health Authorities) (Samarbeidsavtaler mellom de regionale helseforetakene og LFH), 1 January 2014;

approval of the health institution before entering in the agreement or approval of fees for consulting activity etc.)[241].

Meals, travel and accommodation expenses

See above: "Sponsorship of HCPs for attendance at Third Party Organised Educational Conferences"[242].

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[243].

[241] Medtek Norge publication "Clear rules for interaction" and Agreements with Health Authorities; Agreement between LFH and the Norwegian Medical Association laying out the guidelines for cooperation and collaboration between physicians, the Medical Association and the LFH members (Agreement with Medical Association) (Avtale mellom Leverandørforeningen for helsesektoren og Den norske legeforening om Retningslinjer for samarbeid og samhandling mellom leger, Legeforeningen og medlemmer av Leverandørforeningen for helsesektoren), October 2008.
[242]Medtek Norge publication "Clear rules for interaction" and Agreements with Health Authorities
[243]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

IN VITRO DIAGNOSTICS: LABNORGE

Updated: 26 September 2017

General update on the national code

The LabNorge[244] Ethical guidelines[245] ("LabNorge Code") (Lab Norge Etiske retningslinjer), were adopted on 9 April 2003 and last revised in October 2013 (name changed from NLF to Lab Norge). LabNorge will not transpose the MTE Code at this time, but recognizes it as the European industry standard. To that end, LabNorge is committed to actively promoting the MTE Code as a best practice toward its members.

Procedural highlights

LabNorge enforces its Code via its Ethics Council that is composed of the Lab Norge Board. There is an appeals process through which the claimants can seek review by the General Assembly. LabNorge does not have separate Competition Law guidelines, apart from a few remarks in the Ethical guidelines.

Financial support of HCPs for attendance at Third Party Organised Educational Conferences,

The LabNorge Code does not impose specific limits in this area, but the association has issued guidelines on exhibitions[246] (Veiledende retningslinjer for utstillinger) related to national meetings, seminars, etc. The guidelines include conditions and a check list for the organisers. If the event complies with the guidelines, LabNorge may circulate the information about the event among its members.

Arrangements with consultants

The LabNorge Code of Ethics does not impose specific limits in this area.

Meals, travel and accommodation expenses

The LabNorge Code of Ethics does not impose specific limits in this area.

Gifts

Please note that the Norwegian Law on Health Personnel, as referenced above, also applies to IVD products, and therefore the prohibition on gifts also applies to this sector.

[244] LabNorge is the Norwegian industry association for in-vitro diagnostics companies: http://labnorge.no/
[245] There is no English version available.
[246] Guidelines on exhibitions (Veiledende retningslinjer for utstillinger), June 2011

POLAND

MEDICAL DEVICES: POLMED

Updated: 26 September 2017

General update on the national code

The POLMED[247] Code of Business Practice ("POLMED Code") (Kodeks Dobrych Praktyk rynku wyrobów medycznych) was approved on 8 April 2009. The English version is also available on the POLMED homepage. POLMED is currently working on transposing the MTE Code and plans to incorporate both the MTE English version and the Polish language version. The POLMED General Assembly will vote to incorporate the MTE English version into the organization's statutes. Subsequently the Polish language version of the Code will go to the Management Board for passage by resolution. The Polish version of the Code will not change any of the MTE Code's rules; it will simply adjust some language and concepts to the Polish legal landscape. POLMED's aim is to have the new Code in force by the end of 2017.

Procedural highlights

The current POLMED Code is enforced by the Disciplinary Court, which is composed of association members[248]. Appeals may then be made to the Appeals Court. POLMED's Code contains general guidelines on complying with Competition Law[249].

Financial support of HCPs for attendance at Third Party Organised Educational Conferences

POLMED member companies are currently allowed to sponsor individual HCPs to attend Third Party Organised Educational Conferences[250]. Such sponsorship is limited to registration costs as well as cost for travel, lodging and meals[251]. Moreover, notification to hierarchy or employer is required[252].

Arrangements with consultants

The POLMED Code authorises consulting agreements under the conditions laid down in Article 3.5[253]:

- Agreements should be made in writing and in accordance with the Polish law. They should disclose the scope and the object of the agreement
- The remuneration of the consultant should be of fair market value and commensurate to the delivered services
- The agreement should have a legitimate purpose identified in advance

[247] POLMED is the most important organization in Poland for representing the medical devices industry: http://www.polmed.org.pl/
[248] Art. 4.2, Chapter IV, POLMED Code of Ethical Business Practices of market of medical devices (POLMED Code) (Kodeks Dobrych Praktyk rynku wyrobów medycznych), 8 April 2009
[249] Art. 1.3, Chapter IV, POLMED Code
[250] Once the new POLMED Code comes into force direct sponsorship will no longer be permitted
[251] Art. 3.3, Chapter III, POLMED Code
[252] Art. 2.2, Chapter II, POLMED Code
[253] For all conditions see Art. 3.5, Chapter III, POLMED Code

- The selection of the consultant should be based on their expertise and qualifications
- The place and circumstances of the meetings with consultants should be relevant to the subject matter of the consultations and hospitality provided should be of modest value and of secondary importance to the meeting's general objective, etc.

Meals, travel and accommodation expenses

The POLMED Code does not provide any maximum amount for meals, travels and lodging. However, the Code clearly states that any act of hospitality provided to the HCPs should remain in strict relevance to the general purpose of the event and should only cover the following costs: (i) Travel (economy class if the travel time does not exceed 6 hours, otherwise business class is accepted); (ii) Lodging (standard class hotels); (iii) Meals; (iv) Registration fees related to the participation in the meeting[254].

Gifts

Branded and non-branded items up to PLN 100 (around EUR 24, VAT included) are accepted and may be related to the HCP's practice[255].

[254] Art. 3.3, Chapter III, POLMED Code
[255] Art. 3.6, Chapter III, POLMED Code.

IN VITRO DIAGNOSTICS: IPDDL

Updated: 25 September 2017

General update on the national code

In February 2016 IPDDL 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 IPDDL Code, which the working group approved and sent to the IPDDL Board in November 2016. In December 2016 the new IPDDL Code of Ethics ("IPDDL Code") (Kodeks Etyki branży technologii medycznych) was approved and went into force on 1 January 2017[256].

Procedural highlights

IPDDL's has translated and published a Procedural Framework; however, the IPDDL Code provides for a transitional period from 1 January 2017 to 31 December 2017[257]. During this time disputes over the IPDDL Code will be resolved according to the provisions laid out in Part 2. Accordingly, the IPDDL Code is enforced by the Peer Tribunal, which is formed by members of IPDDL that rotate for each case[258]. Appeals can be made to the Appeal Board, also formed by members of IPDDL which rotate for each new case[259]. As the IPDDL Code is a transposition of the MTE Code, it no longer contains specific Competition Law Guidelines.

Financial support of HCPs for attendance at Third Party Organised Educational Conferences

As mentioned above, IPDDL's Code came into force on 1 January 2017 and is a transposition of the MTE Code. Therefore, it also includes a transition period that runs until 31 December 2017, to allow its member companies time to phase out direct support of HCPs at Third Party Educational Conferences. After the end of this Transition Period—on 31 December 2017—support of individual HCPs to attend Third Party Organised Educational Conferences shall no longer be permitted under the new Code[260]. From that point on, Educational Grants become the only way to provide financial support to healthcare professionals to attend Third Party Educational Conferences. Therefore, until the end of this Transition Period (31 December 2017), direct sponsorship of HCPs is still deemed appropriate and thus, must follow the requirements specified in the Code.

As the IPDDL Code is identical to that of MTE, it provides for the same definition of and procedure for Educational Grants[261]. IPDDL has also created for the use of its members a Grant Request Application Form, as well as an Educational Grant Agreement template.

Arrangements with consultants

Please refer to the MTE Code section on arrangement with consultants[262].

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[256] IPDDL Code of Ethics (IPDDL Code), Kodeks Etyki branży technologii medycznych, December 2016
[257] Part 2 : Dispute Resolution Rules, p 21, IPDDL Code
[258] Id.
[259] Id.
[260] Wdrażanie i Okres przejściowy (Deployment and Transition Period), p 4, IPDDL Code, December 2016
[261] Ch. 4 - Granty i Darowizny Charytatywne (Grants and Charity Donations), p 11-12, IPDDL Code, December 2016

Meals, travel and accommodation expenses

Please refer to the MTE Code section on General Criteria for Events[263].

Gifts

Please refer to the MTE Code section on Educational Items and Gifts[264].

Transparency

IPDDL is currently working on disclosure guidelines that will lay out where and how Educational Grants will be documented and publicly disclosed.

[262] Part 1 Ch. 5 – Arrangements with Consultants; IPDDL Code, Rozdział 5: Umowy z HCP o świadczenie usług
[263] Part 1 Ch. 1 – General Criteria for Events; IPDDL Code CZĘŚĆ 1: Wytyczne w zakresie współpracy z HCP i HCO
[264] Part 1 Ch. 8 – Educational Items & Gifts; IPDDL Code, Rozdział 8: Artykuły edukacyjne i upominki

PORTUGAL

MEDICAL DEVICES: APORMED

Updated: 30 August 2017

General update on the national code

APORMED[265] approved its Code[266] ("APORMED Code") (Código de Boas Práticas Comerciais) on 30 March 2010. This Code is a direct translation of the Eucomed Guidelines on Interactions with Healthcare Professionals.

However, APORMED is in the midst of revising its Code in conformity with the MTE Code. Currently, a Working Group is in charge of the revision process and is at work transposing it[267]. After the MTE Code has been fully reviewed and adapted to fit the legal and regulatory landscape in Portugal, the new APORMED Code will be sent to its Board of Directors for consideration. Ultimately, APORMED hopes to vote the final Code at its Annual General Assembly in November 2017, proposing in the vote two options for its entry into force: or 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.

Procedural highlights

APORMED's Disciplinary Committee, which was created by APORMED Statutes, is tasked with enforcing its Code[268] as well as the application of APORMED statutes. It is composed of three members including the President of the General Assembly, the Chairman of the Fiscal Council, and an independent professional appointed by the Board[269].

In parallel, APORMED is reviewing its specific Competition Law guidelines, which will be disclosed as soon as possible. APORMED already organized a training session for its members on this subject.

Financial support of HCPs for attendance at Third Party Organised Educational Conferences

It is important to note that until APORMED transposes and approves a new Code, the 2010 Code remains in force. However, once transposition is complete it plans to adopt the new Code in its entirety—including the prohibition on direct sponsorship.

The 2010 APORMED Code[270] provides that, where permitted under national and local laws[271], regulations and professional codes of conduct, members may provide financial support to cover the

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[265] APORMED, Associação Portuguesa das Empresas de Dispositivos Médicos, is the main association representing the medical technology industry in Portugal: http://www.apormed.pt/?p=ApormedPage&NewsId=15
[266] There is no English version available.
[267] APORMED adota código de ética europeu, 16 January 2017, available here
[268] Art. 9º and 9º-A, APORMED Statutes, 27 March 2012, available at : http://www.apormed.pt/images/Estatutos_Act_Abril.pdf
[269] Art. 9º-B(1), APORMED Statutes, 27 March 2012
[270] The APORMED Code is a translation of the Eucomed Guidelines on Interactions with Healthcare Professionals

cost of conference attendance by individual HCPs[272]. Such financial support should be limited to the conference registration fee and reasonable hospitality costs relating to attendance at the event. Furthermore, prior written notification to the HCP's employer (or other locally-designated body) is required whenever a member makes a financial contribution to the HCP's[273].

On February 5th 2017, the Decree-Law on Transparency and Publicity of Medical Devices came into force[274]. This Decree-Law prohibits the sponsoring or holding of any promotional activities or events in hospitals (i.e. within the services and establishments of the Portuguese National Health Service (NHS))[275]. However, the law also includes an exception to this prohibition that hospitals may request for the sponsoring[276]. The authorization from INFARMED[277], the national regulatory agency, is needed whenever there is an indirect sponsoring from companies to the NHS (i.e. Educational Grants or sponsorship for a scientific event)[278]. Scientific activities can still occur within the premises of the NHS, even if sponsored by companies[279], as well as the regular activities of medical delegates.

Arrangements with consultants

Prior written notification should be made to the hospital administration, the HCP's superior or other locally-designed competent authority. Moreover, consulting agreements should comply with the criteria laid down in Section V of the APORMED Code[280]:

- Consulting agreements should have a legitimate purpose identified in advance.
- Consulting agreements should be made in writing and should fully disclose the purpose and the scope of the agreement.
- Compensation paid to the HCP should be the fair market value for the services provided and should not be tied in any way to the value of medical devices which the consultants may use for their own practice, etc.

Meals, travel and accommodation expenses

Meals, travels and lodging should be reasonable in value and in connection with the event[281].

Gifts

The APORMED Code authorises gifts if they are modest in value and related to the HPC's practice, benefit patients or serve a genuine educational function. Gifts must not be given in the form of cash or cash equivalents[282]. The modest value is fixed up to 60 euros[283].

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[271] There are currently two main decrees governing interactions between medical device companies and HCPs: Decreto-Lei n.º 145/2009, de 17 de Junho (Legislative Decree No. 145/2009 of 17 June) and Decreto-Lei nº 5/2017 (Portuguese Legislative Decree No. 5/2017 of 6 January 2017)
[272] Oncethe new APORMED Code enters into force, , this direct sponsorship of HCPs will no longer be permitted
[273] Section III, APORMED Code of Good Business Practices (APORMED Code) (Código de Boas Práticas Comerciais), 30 March 2010
[274] 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)
[275] Art. 9(3), Portuguese Legislative Decree No. 5/2017 of 6 January 2017
[276] Art. 9(2), Portuguese Legislative Decree No. 5/2017 of 6 January 2017
[277] The Portuguese National Authority of Medicines and Health Products
[278] Based on information from APORMED
[279] But if it involves sponsorship, there is the need of an authorization.
[280] For the rest of the criteria see Section V of the APORMED Code
[281] Section III, APORMED Code

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).[284] The decree law stipulates that any benefit above sixty 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[285]. Consequently, Educational Grants would appear to qualify as a "benefit" and therefore need to be registered on the INFARMED platform.

Furthermore, any sponsorship for an event must be notified to INFARMED 10 days prior the organisation of the event with the agenda, the date and the localisation of the event[286].

[282] Section VI, APORMED Code and Article 51(1) of Legislative Decree No. 145/2009
[283] In accordance with the Order nº1542/2017 (Despacho nº1542/2017)
[284] Art. 11 (5) and following, Portuguese Legislative Decree No. 5/2017 of 6 January 2017
[285] Art. 52(5), Portuguese Legislative Decree No. 5/2017 of 6 January 2017
[286] Art. 11 (1) Portuguese Legislative Decree No. 5/2017 of 6 January 2017

IN VITRO DIAGNOSTICS: APIFARMA

Updated: 25 September 2017

General update of the national code:

The APIFARMA[287] Code of Ethics for Promotional Practices of the Pharmaceutical Industry and Interaction with Healthcare Professionals and Institutions, Organizations or Associations comprising Healthcare Professionals ("APIFARMA Code") (APIFARMA - Código Deontológico para as Práticas Promocionais da Indústria Farmacêutica e para as Interacções com os Profissionais de Saúde e Instituições, Oragnizações ou Associações constituídas por Profissionais de Saúde) entered into force on 1 January 2014. Please find the English version here. APIFARMA is currently in the midst of drafting its new Code, which will transpose the MTE Code albeit with a few adjustments to take into account local legislation. After it is completed, the new Code will be submitted to the Board and then subsequently to the General Assembly for approval. APIFARMA is aiming to have its new Code approved by the end of 2017.

Procedural highlights

Under its current Code, APIFARMA's enforcement mechanism is the Council of Ethics[288]. The Council of Ethics is as an independent body and appeals can be made to the General Assembly. APIFARMA does not have Competition Law Guidelines.

Financial support of HCPs for attendance at Third Party Organised Educational Conferences

The APIFARMA Code of Ethics will remain in place, until APIFARMA approves a new Code. The current APIFARMA Code allows for the direct support of HCPs for attendance at Third Party Organised Educational Conferences. The support must comply with the rules on hospitality. The APIFARMA Code provides that hospitality provided for promotional, scientific or educational events should be limited to travel, meals, accommodation and registration costs[289]. As stated above, APIFARMA's aim is to have its new Code approved by the end of 2017 and as a result from that point direct sponsorship of HCPs will no longer be allowed. However, until the new code is approved, direct sponsorship is still permitted.

For summary of the Law on Transparency and Publicity of Medical Devices that came into force on 5 February 2017, please see the APORMED Section above.

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[287] APIFARMA is the Portuguese association of the pharmaceutical and In Vitro Diagnostics industries: http://www.apifarma.pt/Paginas/default.aspx; Code of Ethics for Promotion Practices of the Pharmaceutical Industry and Interaction with Health Care Professionals and Institutions, Organizations or Associations Comprising Health Care Professionals (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), 9 December 2013("the Code")

[288] Art. 30(1), APIFARMA Code

[289] Art. 18(1), APIFARMA Code

Arrangements with consultants

APIFARMA members are allowed to engage in consultancy agreements with HCPs provided that; there is a written contract specifying the scope and terms of payment, the HCP is selected according to the needs of the project and independently of any incentive to prescribe, recommend or otherwise influence the purchase of the member company's products, the number of hired consultants is reasonable, all documentation is kept and the HCP identifies him or herself clearly as consultant of the member company when some public disclosure of the work is conducted[290].

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 condition to 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[291].

Gifts

The APIFARMA Code authorises 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 form of cash or cash equivalents. The Code also establishes that "low cash value" is to be understood as less than 25€[292].

Transparency

The February 2017 Law on Transparency and Publicity of Medical Devices also extended the transparency system that was already in place for medical and pharmaceutical products to medical devices. It mandates that all benefits granted to a HCP or an entity—financial or otherwise—are reported to the Portuguese National Authority of Medicines and Health Products (INFARMED).[293] The law stipulates that any benefit above sixty euros must be reported to INFARMED on its Transparency and Publicity platform[294]. This must be done within thirty days from the date of the benefit[295]. Consequently, Educational Grants would appear to qualify as a "benefit" and therefore need to be registered on the INFARMED platform.

[290] Art. 22, APIFARMA Code
[291] Art. 18(5), APIFARMA Code
[292] Art. 13, APIFARMA Codeand Article 51.1 of Legislative Decree No. 145/2009
[293] Art. 11, Portuguese Legislative Decree No. 5/2017 of 6 January 2017
[294] Transparência e Publicidade (Transparency Platform), Infarmed, (last visited 25 September 2017)
[295] Art. 52(5), Portuguese Legislative Decree No. 5/2017 of 6 January 2017

ROMANIA

MEDICAL DEVICES & IN VITRO DIAGNOSTICS: AFPM

Updated: 5 October 2017[296]

General update on the national code

On 1 September 2010 AFPM[297] adopted the Eucomed Guidelines on Interactions with Healthcare Professionals as its Code of Ethics ("AFPM Code") (Cod de Conduită şi Etică în Afacer). AFPM is currently discussing how best to bring its current Code in line with the MTE Code.

Procedural highlights

AFPM's current Code is enforced by its Compliance Committee. It was established in 2010, and is composed of external stakeholders. AFPM does not provide separate Competition Law guidelines.

Financial support of HCPs for attendance at Third Party Organised Educational Conferences

In September 2010 AFPM adopted the Eucomed Guidelines on Interactions with HCPs and, as a result, follows the same rules as Eucomed. Therefore, where permitted under national and local laws, regulations and professional codes of conduct, members may provide financial support to cover the cost of conference attendance by individual HCPs. Such financial support should be limited to the conference registration fee and reasonable travel, meals and accommodation costs relating to attendance at the event. In addition, it is required that prior written notification of the sponsorship is made to the hospital administration, the HCP's superior or other locally-designated national authority[298].

Arrangements with consultants

Where no national requirements are prescribed, members shall maintain appropriate transparency by requiring 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. Moreover, consulting agreements should comply with the criteria laid down in Section V of the APFM Code[299]:

- Consulting agreements should be entered into with a legitimate purpose identified in advance
- Consulting agreements should be made in writing, in accordance with local and national laws and should fully disclose the purpose and the scope of the agreement
- The compensation of the HCP 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 consultants may use for their own practice, etc.

[296] This section has not been reviewed by the national association
[297] AFPM is the Romanian Medical Products Suppliers Association: http://www.afpm.ro/
[298] Section III, Code of Medical Products Suppliers Association (AFPM Code) (Codul Asociatiei Furnizorilor de Produse Medicale), September 2010
[299] For the rest of the criteria see Section V of the AFPM Code

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[300].

Gifts

Gifts are permitted if they are modest in value and in accordance with the national and local laws. Also, gifts must relate to the HPC's practice, benefit patients or serve a genuine educational function. Gifts must not be given in the form of cash or cash equivalents[301].

Transparency

In February 2014 Romania amended the Healthcare Reform Law and introduced certain transparency provisions in 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[302]. Companies also have to publish this information on their websites. The deadline for the reporting of the data to the ANMDM was the 31 March 2016, and the deadline for publishing the information on the company's website is the 31 October 2015[303]. In 2017, the deadline for companies to report their data to the ANMDM should be the 31 March 2017.[304] The submission must be made in Romanian, specifying the value of the financial contributions in Romanian Leus (RON), and through a specific form[305], both electronically and in hard copy.

[300] Section III, AFPM Code
[301] Section VI, AFPM Code
[302] 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)
[303] 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.
[304] Based on the information from the Ministry of Health.
[305] The form can be found in Order 874/2015, Annex I.

RUSSIA

MEDICAL DEVICES: IMEDA

General update on the national code

The IMEDA[306] Code of Ethics ("IMEDA Code") (IMEDA Этический кодекс компаний - производителей медицинских изделий) was last amended in 2013. An English version is also available on the IMEDA homepage. IMEDA created a working group responsible for a new IMEDA Code, which has already taken the MTE Code and translated it into Russian. For the remainder of 2017 it will continue to review and identify which parts of the MTE Code will need to be adjusted to fit the specific legal and regulatory environment in Russia. IMEDA aims to propose a new Code sometime between 2018 and 2019.

Procedural highlights

IMEDA currently does not have an enforcement mechanism for its Code and also does not provide Competition law guidelines.

Financial support of HCPs for attendance at Third Party Organised Educational Conferences

Direct sponsorship of individual HCPs to attend Third Party Organised Educational Conferences has been prohibited by law in Russia since 2011[307]. *Indirect* sponsorship (e.g. Educational Grants); however, is still permitted. For example, a company may still sponsor a Third Party Organised Educational Event via grant to a congress organiser or a healthcare institution as long as the attending HCPs are not chosen by a sponsoring company[308].

Arrangements with consultants

According to the Law on Health Protection, HCPs are allowed to 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[309]. 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 Section 2 of the IMEDA Code have to 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.[310].

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[306] IMEDA is the Russian medical device industry association: http://www.imeda.ru/

[307] 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)

[308] IMEDA Code of Ethical Conduct for Interactions with Healthcare Professionals (IMEDA Code) (Кодексэтичногоповеденияпривзаимодействииссработникамиздравоохранения), Section 3, p 3-4, 2013

[309] Art. 74, par. 1, p 1, Law 323

[310] All conditions are laid down in Section 2 of the IMEDA Code

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 new IMEDA Code provides that member companies are not allowed directly or through third parties (e.g. travel agencies, distributors, etc.) 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 received from the member companies to cover reasonable expenses related to HCPs' participation in such conferences[311]. In addition, according to the new 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. Entertainment is not allowed in relation to such meals, neither attendance of spouses nor other guests of HCPs[312].

Gifts

Any gifts, including those in the form of cash, or payments for entertainment and holiday travel, are not allowed under the Law on Health Protection[313].

The IMEDA Code makes a difference between educational items and gifts. According to the Code, the following should be considered as a gift and, as a result, not allowed[314]:

- Cash, food, wine or spirits, gift baskets, gift cards/certificates, or flowers; and
- Any type of non-educational promotional items, even if of minimal value, related to HCP's practice or benefit patients.

[311] Section 3, IMEDA Code and Q&A 5, Questions and Answers (Q&A) Relating to the International Medical Device Manufacturers Association (IMEDA) Code of Ethical Conduct for Interactions with Healthcare Professionals (IMDEA Q&A) (ВопросыиОтветы (Q&A) поКодексуэтическогоповеденияпривзаимодействииссработникамиздравоохранения), 2013
[312] Section 3, IMEDA Code
[313] Art. 74, par. 1, p. 1, Law 323
[314] Section 7, IMEDA Code

SLOVAKIA

MEDICAL DEVICES: SK-MED

Updated: 2 October 2017

General update on the national code

The SK-MED[315] Code of Ethics ("SK-MED Code") (ETICKÝ KÓDEX Slovenskej asociácie dodávateľov zdravotníckych pomôcok SK- MED) was adopted on 1 January 2013. There is also an English translation available. SK-MED is currently in discussions to transpose the MTE Code—more information forthcoming.

Procedural highlights

SK-MED's current Code is enforced through its Ethics Committee, which was created in 2006 and is composed of association members and one external lawyer. Appeals can be made to the General Assembly. SK-MED does not have Competition Law guidelines.

Financial support of HCPs for attendance at Third Party Organised Educational Conferences

Under the current SK-MED Code, member companies may sponsor individual HCPs to attend purely educational events organised by third parties. The HCPs are allowed to accept such support only in relation to educational events. Law 362/2011 which came into force on 1 December 2011 introduced some limitations to the pharma sector related to the sponsorship of HCPs to attend certain events[316]. However, these limitations do not apply to the medical device companies.

The SK-MED Code allows covering conference attendance costs of the 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[317].

Arrangements with consultants

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 criteria provided in Section V of the Code[318]:

- The contract must specify the services to be provided by the HCP and must conform to valid Slovak legal regulations

[315] SK-MED is the Slovak Medical Devices association: http://www.skmed.sk/
[316] 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.
[317] 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
[318] For all criteria please see Section V of the SK-MED Code of Ethics

- 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.

Meals, travel and accommodation expenses

According to the SK-MED Code, members may cover reasonable travel and accommodation expenses in accordance with Slovak legal regulations[319].

Gifts

The SK-MED Code provides that it is permitted to offer 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[320].

Transparency

Law 362/2011 amended some other legislation and introduced certain reporting obligations to the pharma companies as well as the HCPs. For the 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 to the 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.

[319] Section III, SK-MED Code of Ethics
[320] Section VI, SK-MED Code of Ethics

IN VITRO DIAGNOSTICS: SEDMA

Updated: 4 October 2017[321]

General update on the national code

SEDMA[322] currently does not have its own Code of Ethics, but applies the EDMA Code of Conduct. SEDMA has translated the MTE Code into Slovakian and this new Code will come into force 1 January 2018[323].

Procedural highlights

SEDMA does not currently have an enforcement mechanism for its Code. SEDMA does not provide separate Competition Law guidelines.

Financial support of HCPs for attendance at Third Party Organised Educational Conferences

SEDMA currently applies the EDMA Code of Conduct..

Arrangements with consultants

Please see information above.

Gifts

SEDMA currently has no special provisions on the agreement gifts other than the requirements of the EDMA Code.

Transparency

Please refer to the Transparency section of the Medical Devices chapter on Slovakia for an overview of the legal framework in Slovakia.

[321] This section has not been reviewed by the national association
[322] SEDMA is the Slovak Association of In vitro Diagnostics manufacturers and suppliers: http://www.sedma-ivd.sk/
[323] Etický kódex obchodných praktík MedTech Europe (MedTech Europe Code of Business Ethics), 2016 (last visited 4 october 2017)

SLOVENIA

MEDICAL DEVICES: SLO-MED

Updated: 29 August 2017

General update on the national code

The SLO-MED Code of Conduct[324] ("SLO-MED Code") (Kodeks Slo-Med) entered into force in 2014 and was last modified on 27 June 2015. There is currently a joint working group in place, which is finalizing a strategy plan for transposition of the MTE Code. An update should be forthcoming fall 2017.

Procedural highlights

SLO-MED plans to set up an enforcement body—known as the Council for Conformity—that will monitor compliance with its new Code.[325]

Financial support of HCPs for attendance at Third Party Organised Educational Conferences

According to SLO-MED, in Slovenia, direct sponsorship of individual HCPs to attend Third Party Organised Educational Conferences is not allowed[326][327]. Indirect sponsorship in the form of Educational Grants needs to be with the hospital which is responsible for selecting the attendees[328].

Arrangements with consultants

SLO-MED's Code does not provide specific detailed rules for interactions with HCPs. Nevertheless, according to the SLO-MED Code, SLO-MED members are required to comply with the Eucomed Code[329]. Therefore, the rules regarding agreements with consultants are the same as those in the Eucomed Code.

Meals, travel and accommodation expenses

There are no special provisions on the agreement regarding meals, travel and accommodation expenses other than the requirements of the Eucomed Code.

Gifts

There are no special provisions in the agreement on gifts other than the requirements of the Eucomed Code. However, Slovenian law does impose restrictions on gifts to individuals working in the public

[324] There is no English version available of this document.
[325] SLO-MED website (last visited 6 September 2017)
[326] Decree on the limitations and duties imposed upon public servants with respect to receiving gifts (Ur.l. RS št. 58/03 and 56/15).
[327] Art. 11, Part II, Civil Servants Act (Ur. l. RS št. 63/07)
[328] Based on information from SLO-MED
[329] Art. 2, SLO-MED Code of Conduct (KODEKS SLO-MED), 27 May 2015

sector[330]. 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[331].

Transparency

There are no specific regulations on financial transparency applicable, only a generic Integrity Law[332] which does not impose disclosing obligations on life sciences companies.

[330] Art. 3, Decree on the limitations and duties imposed upon public servants with respect to receiving gifts (Ur.l. RS št. 58/03 and 56/15).
[331] Art. 2(3), Decree on the limitations and duties imposed upon public servants with respect to receiving gifts (Ur.l. RS št. 58/03 and 56/15).
[332] Integrity and prevention of corruption act (ZintPK)

IN VITRO DIAGNOSTICS: SIEDMA

Updated: 11 September 2017

General update on the national code

In April 2014 SIEDMA adopted an extended interpretation of the EDMA Code of Ethics for SIEDMA's members (Razširjena razlaga etičnega kodeksa EDMA za člane SIEDMA). Compliance with the EDMA Code of Ethics is mandatory for SIEDMA members. The EDMA Code of Ethics in Slovenian is uploaded on SIEDMA's website. Currently, SIEDMA has a joint working group in place that is working on a new Code, which it plans to be a direct transposition of the MTE Code.

Procedural highlights

In April 2014, SIEDMA approved the regulation on the functioning of the Commission for Ethics. According to the regulation any infringement of the applicable Code of Ethics is evaluated by the Commission for Ethics[333].The Commission consists of 3 members (the Chair and two members). Members of the Commission are randomly nominated from the SIEDMA representatives who are not a party to the reported case. Appeals are made to the Commission itself. SIEDMA itself does not issue separate Competition Law guidelines to its members.

Financial support of HCPs for attendance at Third Party Organised Educational Conferences

Until SIEDMA passes and approves a new Code, members of SIEDMA will continue to primarily be subject to the EDMA Code of Ethics[334].

However, it is important to highlight that while the EDMA Code of Ethics provides[335] that Members may cover conference costs and reasonable travel and lodging expenses of HCPs attending conferences primarily dedicated to promoting objective scientific and educational activities, local legislation in Slovenia prohibits direct sponsorship[336]. Slovenia's Law on Civil Servants[337] touches on the behaviour between industry and the public sector and direct sponsorship is not used. Currently, grants and donations are used in order to provide financial support to the public sector (e.g. HCPs). A public healthcare institution 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 Organized Educational Conference.

Arrangements with consultants

There are no special provisions on the agreement regarding agreements with consultants other than the requirements of the EDMA Code of Ethics.

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[334] Extended interpretation of the EDMA Code of Ethics for members of SIEDMA (Razširjena razlaga etičnega kodeksa EDMA za člane SIEDMA), April 2014
[335] EDMA Code of Ethics, Part A, II. Supporting Third Party Organised Educational Conferences
[336] See SLO-MED section, FNs 299 & 300
[337] Civil Servants Act (Ur. l. RS št. 63/07)

Meals, travel and accommodation expenses

The extended interpretation agreed upon on April 2014 covers concepts such as location of events, venue and accommodation selection, entertainment, and travel expenses.

- Accommodation: the selected location and the hotel should not be the main attraction of the event. The hotel will not normally be luxurious, nor should it be known for its offer of entertainment, even if the hotel downgrades its category to a lower one to attract the conference or event. The event should not be organised at the location in the high touristic season (e.g. winter – ski resort hotel). SIEDMA members may organize events for local HCPs only in Slovenia. Exceptions are acceptable for customer trainings or reference site visits that are not feasible within the country and events that are organised by corporate members on an international level. In any case, events with local HCP participation must be in accordance with the EDMA Code of Ethics.
- Travel expenses and meals: The support provided by members to cover travel and accommodation costs must be strictly adapted to the duration of the congress or educational event.

Gifts

There are no special provisions on the agreement gifts other than the requirements of the EDMA Code of Ethics. However, see SLO-MED section on gifts for Slovenian national requirements[338].

[338] Art. 2(3) & Art. 3, Decree on the limitations and duties imposed upon public servants with respect to receiving gifts (Ur.l. RS št. 58/03 and 56/15).

SPAIN

MEDICAL DEVICES & IN VITRO DIAGNOSTICS: FENIN

Updated: 26 September 2017

General update on the national code

The FENIN[339] Code of Good Practices ("CGP")[340] (Código de Buenas Prácticas de Fenin) was last revised in 2009. Further to this, FENIN also published a Question & Answer document (Documento de preguntas y respuestas sobre el CBP de Fenin).

However, on 20 December 2016 FENIN formally approved its new Code of Ethics of the Healthcare Technology Sector[341] (Código Etico del Sector de Tecnologia Sanitaria). The FENIN Code will enter into force on 1 January 2018[342]. This new FENIN Code is a transposition of the MTE Code, with the exception of a few small differences, which are discussed below.

Procedural highlights

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[343]. The Deontological Committee is appointed by FENIN's Board of Directors, the Ethics and Compliance Unit reports to the General Secretariat and will have full independence from the governing bodies of the Federation, Autocontrol will be in charge of compliance and interpretation of the Code and there is no appeal possible once Autocontrol has taken its decision[344]. Meanwhile, the Monitoring Committee will be responsible for analysing the implementation of the Code and proposing any revisions to the Code[345]. FENIN does not provide Competition Guidelines; however, the new FENIN Code does include a reference to complying with all regulations in order to respect free market competition[346].

Financial support of HCPs for attendance at Third Party Organised Educational Conferences

As discussed above, the new FENIN Code does not come into force until 1 January 2018. Therefore, until that time the CGP remains in force. According to the CGP (and until December 31, 2017), sponsorship of HCPs to attend certified scientific events is allowed if such events are organized by

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[339] FENIN is the Spanish association representing medical technology manufacturers, importers and distributors: http://www.fenin.es/en/
[340] There is no English version available.
[341] FENIN Code of Ethics of the Healthcare Technology Sector (FENIN Code) (Código Etico del Sector de Tecnologia Sanitaria), August 2016. English version available here: http://panelfenin.es/uploads/fenin/documentacion_buenas_practicas/documento_23.pdf (last visited 26 September 2017)
[342] Ch. XX, p 58, FENIN Code
[343] Ch. XIX, p 45, FENIN Code
[344] Ch. XIX, p 45-49, FENIN Code
[345] Ch. XIX, p 50-51, FENIN Code
[346] Ch. XVIII, p 44, FENIN Code

acknowledged agencies and are certified to be of scientific interest[347]. Sponsor should only cover registration fees as well as costs for travel, accommodation and meals in relation to the event[348]. Medical and scientific aspects should be the main focus of the event and any hospitality offered during such events should be always reasonable[349]. There are no legal prior authorisation/notification requirements that apply.

However, as of 1 January 2018 direct sponsorship will no longer be allowed and member companies will only be able to offer financial support to hold Third Party Organised Educational Events through training grants, which may also be used to fund HCPs to attend educational conferences[350]. Nevertheless, these grants may not be given directly to the individual HCPs[351]. Additionally, all events must comply with the remainder of the Code's rules, including approval by the Event Validation System[352].

Arrangements with consultants

The CGP also authorizes the consulting agreements with professionals according to certain criteria, some of which include the following[353]:

- Agreement with HCP should be recorded in writing and should specify the services to be provided as well as compensation paid for such services.
- Financial compensation of the consultant should be fair market value and proportioned to the service(s) rendered.
- Services should not be tied in any way to the past/future use of the member's device or service, etc.

Meals, travel and accommodation expenses

The CGP provides that sponsorship of HCP for attendance at Third Party Organised Educational Conferences is limited to the payment of registration fees, travel expenses, accommodation and meals. These expenses should be related to the objective of the event and be reasonable[354]. The New FENIN Code provides for similar parameters. It states that flights should be economy class, unless over five hours, in which case business will be allowed and for train rides economy tickets should also be purchased, unless travel is longer than two hours[355]. The FENIN Code states that amounts provided for meals should not exceed 60 euros[356]. 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

[347] Art. 2.1 CGP
[348] Art. 2.2, CGP
[349] Art. 2.3, CGP
[350] Ch. VII, p 14 & 19, FENIN Code
[351] Id.
[352] For MTE members it will be CVS and for others outside this scope it will be the conference review system of the FENIN Ethics and Compliance Unit
[353] Ch. IX, p 25-26, FENIN Code (see the chapter for the complete list of conditions)
[354] Art. 2, CGP
[355] Ch. VI(5), p 17, FENIN Code
[356] Ch. VI(4), p 17, FENIN Code

specifies that it must give prior written notification to the manager ("Gerente") of the health center[357]. 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 HCPs are not allowed unless they are of minor value, i.e. less than EUR 10[358]. The gifts over EUR 10 are only acceptable if they have a genuine training role for the HCPs and benefit directly from the care or assistance of patients (e.g. scientific books or anatomical models)[359].

Transparency

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

Misc.

Under the new FENIN Code, all entities which organize educational events for HCPs may request the Seal of Adherence to the Code of Ethics[360]. 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[361].

[357] Ch. VI(7), p 18, FENIN Code (this is a more specific requirement than included in the MTE Code as it indicates the exact person)
[358] Ch. XVI, p 42, FENIN Code (the CFP previously allowed for gifts up to 30 euros)
[359] Ch. XVI, p 42, FENIN Code
[360] Ch. VII, p 21, FENIN Code
[361] Id.

SWEDEN

MEDICAL DEVICES: SWEDISH MEDTECH

Updated: 21 August 2017

General update on the national code

Swedish Medtech is a party to the Cooperation Agreement (Samverkansavtal) which came into force on 01/01/2014. An English version is also available. The following parties are signatories to the Cooperation Agreement: the Swedish Labtech, Swedish Medtech, Swedish pharmaceutical association (LIF) and Swedish Association of Local Authorities and Regions (SKL). Due to the fact that Swedish Medtech has already aligned with the main principles of the MTE Code via the Cooperation Agreement, there is no revision of its Code planned.

Procedural highlights

Swedish Medtech created and tasked its Dispute Settlement Panel with enforcement of its Cooperation Agreement. It was created in 2006 and it is composed of external stakeholders. Members may appeal the Panel's decisions only if the sanction is the expulsion from the association. Swedish Medtech does not currently provide Competition Law guidelines.

Financial support of HCPs for attendance at Third Party Organised Educational Conferences

Sweden was one of the first countries in Europe to adopt a total ban on both direct and indirect sponsorship (e.g. Educational Grants) for HCPs attending Third Party Organised Educational Conferences. In particular, as of 1 January 2015 companies can no longer cover congress registration, travel, meals and accommodation costs of individual HCPs. The prohibition was introduced by the Cooperation Agreement approved in 2013[362] and applies to any kind of sponsorship for HCPs attending a third party conference. It was signed by the Swedish association of local authorities and regions (i.e. SKL or the county councils and municipalities organisation), the medical technology industry, including Swedish Medtech and Swedish Labtech, and the pharmaceutical industry (LIF).

However, under the Cooperation Agreement, medical device 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[363] may cover all relevant costs for enabling the service information to be carried out, including travel and accommodation.

[362] Section 7b, AGREEMENT REGARDING RULES OF COOPERATION CONCERNING HEALTHCARE FINANCED BY PUBLIC FUNDING, THE PHARMACEUTICAL INDUSTRY, THE MEDICAL TECHNOLOGY INDUSTRY AND THE LABORATORY TECHNOLOGY INDUSTRY (Överenskommelsen för den offentligt finansierade hälso-och sjukvården läkemedelsindustrin medicintekniska industrin och laboratorietekniska industrin) (Cooperation Agreement), November 2013.

[363] 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.

Arrangements with consultants

The assignment has to be agreed upon in writing between HCP, HCP employer and the company. With a public employer, the agreement constitutes a public document. Remuneration for work has to 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[364].

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, medical technology 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.

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[365].

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

Gifts

The Cooperation Agreement does not provide detailed rules on gifts since the rules concerning gifts and giveaways differ between the pharmaceutical industry and medical technology industry. For Swedish MedTech companies, the rules concerning gifts and giveaways in the Eucomed Guidelines on Interactions with HCPs and its Q&A Guidance Document apply.

[364] Section 8, Cooperation Agreement
[365] Section 4b, Cooperation Agreement

IN VITRO DIAGNOSTICS: SWEDISH LABTECH

Updated: 9 September 2017

General update on the national code

Swedish Labtech[366] 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 should apply the Cooperation Agreement between Healthcare Principles Medical Technology, Laboratory Industry, and Pharma[367]. Due to the fact that Swedish Labtech has already aligned with the main principled of the MTE Code via the Cooperation Agreement, there is no revision of its Code planned.

Procedural highlights

Swedish Labtech employs an enforcement mechanism where the Board and an external chair review submitted complaints. The system was created in November 2010 and there is no appeal process. Instead, the parties exchange statements and any other information that they want to share with the Board. Swedish Labtech has Competition Law provisions included in the Business Code.

Since Swedish Labtech, as Swedish Medtech, the Swedish Medical Devices association, is a party to the Cooperation Agreement, please refer to the Swedish Medical Devices chapter above.

[366] Swedish Labtech is the Swedish instrument and diagnostics trade association: http://www.swedishlabtech.se/
[367] Swedish Labetch, Affarskod (Business Code)

SWITZERLAND

MEDICAL DEVICES: SWISS MEDTECH

Updated: 25 August 2017

General update on the national code

On 12 June 2017, FASMED merged with Medical Cluster to create a new medical technology association: SWISS MEDTECH. In 2017 SWISS MEDTECH[368] adopted its Code of Business Conduct ("SWISS MEDTECH Code") (Code SWISS MEDTECH de pratique commerciale éthique) The new SWISS MEDTECH Code, which transposes the MTE Code[369] comes into force as follows:

- 12 June 2017, the SWISS MEDTECH Code entered into force (apart from those sections mentioned below)
- 1 January 2018, the restriction on providing direct material or financial support to HCPs for Training Events Organized by 3rd parties (e.g. direct sponsorship) will come into force.[370]

Procedural highlights

Swiss MEDTECH's Code is enforced by the Legal and Compliance specialist group, which is in charge of its mediation process.[371] The head of this group is the General Counsel, who is elected by the committee of SWISS MEDTECH.[372] FASMED previously provided Competition Law guidelines, which remain in force under the new SWISS MEDTECH association (Wettbewerbsrechtliche Leitlinien fuer die Arbeit im FASMED).

Financial support of HCPs for attendance at Third Party Organised Educational Conferences

While SWISS MEDTECH's Code has already come into force, until 31 December 2017, direct sponsorship remains permitted and its previous rules covering that subject apply. According to its previous Code, applicable disclosure requirements must be observed or necessary approvals obtained when member companies cover the cost of individual HCPs attending Third Party Organised Educational Events. In each case, appropriate transparency should be maintained by obtaining the prior written consent of the hospital administration, the professional's superior or another responsible agency with complete disclosure of the purpose and scope of the sponsoring[373].

However, as of 1 January 2018 the provision banning direct sponsorship of HCPs to attend Third Party Organized Educational Conferences comes into force[374]. At that time Educational Grants

[368] SWISS MEDTECH: https://swiss-medtech.ch/fr/web/swiss-medtech-website
[369] SWISS MEDTECH Code of Business Conduct (SWISS MEDTECH Code) (Code SWISS MEDTECH de pratique commerciale éthique), 12 June 2017. Previously, FASMED had published « Application Guidelines » along with its Code of Business Conduct. However, as of the publication of this handbook SWISS MEDTECH had not published similar application guidelines for its new code.
[370] This restriction is discussed in Chapter 2 and in Section 3 of Chapter 4 of the SWISS MEDTECH Code.
[371] Part 2 Ch. 11 – Autorités compétentes, p 24, SWISS MEDTECH Code, June 2017
[372] Part 2 Ch. 11 – Autorités compétentes, p 24, SWISS MEDTECH Code, June 2017
[373] Art. 3.3a, FASMED Code of Business Conduct (FASMED Code), May 26, 2010
[374] Introduction: Entry into Force, p 7-8, SWISS MEDTECH Code, June 2017

become the only way to provide financial support to HCPs to attend Third Party Organized Educational Conferences. As the SWISS MEDTECH Code is an exact transposition of the MTE Code, the rules governing Educational Grants are the same[375].

In 2015 there was a major change to the Swiss Criminal Code. On 25 September 2015 the anti-corruption provisions were revised. The revisions came into force on 1 July 2016. According to Article 322octies and 322novies, corruption and acts of bribery in the private sector now fall under the Swiss Criminal Code (Stgb).[376] This revision of the law—aptly dubbed "*lex FIFA*"—applies also to the public health sector and could have an impact on 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.[377] 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.[378]

Revisions were also made to Swiss Federal Act on Medicinal Products and Medical Devices (Therapeutic Products Act, TPA).[379] On 18 March 2016, the Swiss National Parliament adopted the revised Therapeutic Products Act (revTPA) and relevant ordinances.[380] Individual provisions and the corresponding ordinance terms will enter into force at the beginning of 2018. However, most of the implementing provisions are being amended. The public consultation phase began on 21 June 2017 and runs until 20 October 2017.[381] After the public consultation it will be determined when the implementing provisions will take effect (likely January 2019).[382] Article 55 of the revised Act includes an integrity provision governing the interaction between industry and HCPs/HCOs.[383] It bans undue advantages provided to or received by HCPs/HCOs and includes a list of permitted advantages. Depending on the drafting of the Ordinances this integrity provision could also cover certain categories of medical devices. The Act also includes certain transparency obligations; however, it appears the revisions pertain mainly to Medicinal products and not Medical Devices.

Arrangements with consultants

Please refer to the MTE Code section on Arrangements with Consultants[384].

Meals, travel and accommodation expenses

Please refer to the MTE Code section on General Criteria for Events[385].

Gifts

Please refer to the MTE Code section on Educational Items and Gifts[386].

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[375] See Section 4, MedTech Europe Code; Ch. 4 Sec. 3 – Subventions de formation, SWISS MEDTECH Code, June 2017
[376] Art, 322octies and Art. 322novies Swiss Criminal Code
[377] Art. 102 Para 2 Swiss Criminal Code
[378] Art. 322decies Swiss Criminal Code
[379] Federal Act on Medicinal Products and Medical Devices (Therapeutic Products Act, TPA) of 18 March 2016
[380] The ordinance legislation is known as the Therapeutic Products Ordinance Package IV
[381] Start of Consultation Procedure for Federal Council and Agency Council Ordinances, available at : SwissMedic
[382] Ordinary Revision of the Swiss Therapeutic Products Act (Stage 2), available on the website of the Swiss Office of Public Health
[383] Federal Act on Medicinal Products and Medical Devices (Therapeutic Products Act, TPA) of 18 March 2016
[384] Part 1 Ch. 5 – Arrangements with Consultants
[385] Part 1 Ch. 1 – General Criteria for Events

IN VITRO DIAGNOSTICS: SVDI

Updated 5 October 2017[387]

General Update on the national code

Currently, SVDI[388] applies the EDMA Code of Conduct. SVDI plans to discuss the revision of its Code.

Procedural highlights

SVD does not provide its own Competition Law Guidelines.

Financial support of HCPs for attendance at Third Party Organised Educational Conferences

SVDI currently does not have a separate Code of ethics and applies the EDMA Code of Conduct in every respect. According to the EDMA Code, Members may provide financial grants to cover conference costs and reasonable travel and lodging expenses of Healthcare Professionals (and medical students, residents, fellows, and others who are Healthcare Professionals in training) when the conference is primarily dedicated to promoting objective scientific and educational activities[389].

Such support should be consistent with the regulations of the country where the Healthcare Professional is licensed to practice[390]. The conference organiser should be responsible for and control the selection of programme content, faculty, educational methods, and materials. The support by a member should be clearly stated in advance of, at the meeting and in the proceedings.

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

Arrangements with consultants

Under the EDMA Code, HCPs may serve as consultants to members, providing valuable bona fide consulting services, including research, participation on advisory boards, presentations at member-sponsored training, and product collaboration. It is appropriate to pay Healthcare Professionals reasonable compensation for performing these services[391]. The EDMA Code also lays out several factors that should be considered when entering into consulting arrangement, including the agreement being in writing, paying consultant compensation, legitimate business purpose for services, etc.[392].

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[386] Part 1 Ch. 8 – Educational Items & Gifts
[387] This section was not reviewed by the national association
[388] SVDI is the Swiss In Vitro Diagnostics industry association: http://www.svdi.ch/d/start.php
[389] Part A(II), Supporting third party educational conferences, p 6, EDMA Code, December 2011
[390] Id.
[391] Part A(IV), Arrangements with Consultants, p 7, EDMA Code, December 2011
[392] Id.

Meals, travel and accommodation expenses

According to the EDMA Code, Members may provide financial support to the conference organiser in the form of modest meals and hospitality for programme attendees. Any meals and hospitality should be modest in value and should be subordinate in time and focus to the purpose of the conference[393].

Gifts

Gifts are allowed under the provisions laid down in the EDMA Code. Members occasionally may provide modest gifts to Healthcare Professionals, but these should be modest in value and in accordance with the regulations of the country where the Healthcare Professional is licensed to practice. As a general rule, gifts should benefit patients or take a genuine educational form[394].

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

[393] Part A(II), Supporting third party educational conferences, p 6, EDMA Code, December 2011
[394] Part A(V), Gifts, p 8, EDMA Code, December 2011

TURKEY

MEDICAL DEVICES & IN VITRO DIAGNOSTICS: ARTED

Updated: 5 October 2017

General update on the national code

ARTED[395] published its revised Code of Ethics[396] ("ARTED Code") on Interactions with Health Care Professionals and Good Practice (Sağlik Mesleği Mensuplari İle İletişim İlkeleri, Etik Kurallar Ve İş Uygulamalari Rehberi) in January 2016. ARTED has communicated to the Secretariat that they do not plan a revision of their current Code since they have completed a review of its Code against all applicable laws. Their request for confirmation that the local legislation in Turkey is equivalent to the Code is currently being considered.

Procedural highlights

ARTD enforces its Code by its Ethics Board, which was created in 2013. It is composed of association members. Appeal can be made to the Supreme Ethics Board. The ARTED Code contains Competition Law guidelines[397].

Financial support of HCPs for attendance at Third Party Organised Educational Conferences

According to the ARTED Code, where permitted by the laws, regulations and principles of good professional practice, the members may provide financial support to cover participation costs of HCPs for training activities and scientific meetings[398]. The scientific purpose of the meeting should not be of secondary importance[399]. Mentioned financial support must be limited to subscription costs and reasonable travel, meals and accommodation costs in relation to HCP's participation. The members must fully comply with the declaration and approval requirements for the sponsorship set forth in the relevant laws and regulations[400].

In 2012 ARTED decided that the members shall not support the participation of HCP for training activities and scientific meetings nor shall they organize a meeting in Northern Cyprus, which is defined as a touristic country and not appropriate for this kind of meetings.

On 15 May 2014, the Turkish government passed a Regulation on the Sales, Advertisement and Promotion of Medical Devices[401]. In addition to other aspects, the Regulation introduced certain rules regulating interactions between medical device companies and HCPs. In particular, the following requirements were introduced for congress sponsorship: (i) companies must submit all the details in

[395] Turkish Association of Research Based Medical Technologies Manufacturers: http://www.arted.org.tr/
[396] For the time being there is no English version available.
[397] Section 5.9, ARTED Code of Ethics on Interactions with Healthcare Professionals and Good Practice (ARTED Code) (Sağlık Mesleği Mensupları ile İletişim İlkeleri, Etik Kurallar ve İş Uygulamaları Rehberi), 2016
[398] Section 5.1, 5.2, ARTED Code
[399] Section 5.2, ARTED Code
[400] Section 5.2.a, ARTED Code
[401] Regulation regarding the Sales, Advertisement and Promotion of Medical Devices (Regulation) (Tıbbi Cihaz Satış, Reklam Ve Tanıtım Yönetmeliği), 15 May 2014

relation to the 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 the attendance takes place; (ii) an HCP can receive maximum four[402] congress sponsorships from companies per year, maximum two of these sponsorships may come from the same company and maximum two of them can be an international congresses; (iii) Congresses, symposia, seminars and meetings to be held or contributed to by the companies shall be notified to the MoH as an annual program before the end of the previous year.

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

- Obtain permission of 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 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 season, which are, for ski resorts, between December 1st and March 1st, and for beach resorts, between June 15th and September 15th[403].

A revision of the Regulation on the Sales, Advertisement and Promotion of Medical Devices is currently on the Turkish government's agenda and various stakeholders, including ARTED, have submitted comments.

A temporary state of emergency was enacted in Turkey on 20 July 2016 which led to the closure of some healthcare institutions and a number of public sector workers have been removed from their posts, including HCPs. Many of the HCPs also had positions in industry and professional associations. In May 2017, this state of emergency was extended once again, indefinitely[404].

Arrangements with consultants

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[405]. In addition, the consultancy contracts between the HCPs and member companies have to comply with the rules outlined in the article 5.3 of the ARTED Code.

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[402] Regulation amending the Regulation regarding the Sales, Advertisement and Promotion of Medical Devices, 25 July 2015 (TIBBİ CİHAZ SATIŞ, REKLAM VE TANITIM YÖNETMELİĞİNDE DEĞİŞİKLİK YAPILMASINA DAİR YÖNETMELİK), Article 4.
[403] Regulation amending the Regulation regarding the Sales, Advertisement and Promotion of Medical Devices, 25 July 2015, Article 4.
[404] U.S. Department of State, "Turkey Travel Warning," 28 September 2017 (last visited 5 October 2017)
[405] Section 5.3, ARTED Code; see also U.S. Department of State, "Turkey Travel Warning," 28 September 2017 (last visited 5 October 2017)

It is important to note that on 18 January 2014 a law[406] came into force which introduced prohibition for all HCPs employed by state and university hospitals to directly 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 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.

However, in 2014, the provisions of the law prohibiting the public HCPs to conduct any private practices have been referred to the Constitution Court for annulment. The Constitution Court annulled merely the specific provision requiring the HCPs to shut down their private clinics, if any, whereas the remaining provisions on general ban on private practice were upheld. Currently, a legal ambiguity exists as the law still does not allow private practice however does not require the HCPs to end their private clinic activities.

Meals, travel and accommodation expenses

According to the ARTED Code, members are allowed to cover reasonable travel, meals and accommodations costs of the HCPs in relation to the scientific meetings organized by third parties[407].

It is important to note here that that the applicable provisions[408] provide two types of meetings with a precise distinction; one being the "**scientific meetings"** where all content is strictly scientific with no product promotion; and the second one being the **"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 conducted in cities where the invited HCPs are assigned to work. Since there is no sponsorship for these events, there are no quota requirements.

With the revisions made on 22 September 2016, a more specific category is introduced by stating that the 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[409] implying that the above mentioned specific conditions will not be required for these types of activities.

In addition, member sponsored hospitality in connection with the consultant meetings must be modest in value; its duration must be parallel with the scientific program and focused on the purpose of the meeting[410.] The ARTED Code does not provide the maximum amounts for hospitality.

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[406] 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
[407] Section 5.2, ARTED Code
[408] The MoH on Communiqué on Scientific Meetings and Educational Activities
[409] 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
[410] Section 5.3, ARTED Code

Gifts

Companies may occasionally offer monetarily modest gifts, having symbolic value, branded or non-branded products provided that they are compliant with the laws, regulations and code of ethics. The gifts must relate to the professional practices of the HCPs, be beneficial for the patients and have an educational function. It is forbidden to give gifts in cash or equivalent to cash[411]. It is important to note that the Regulation introduced a maximum limit for promotional material of 2.5% of the minimum monthly wage (i.e. approximately 10 EUR)[412].

Transparency

On 27 February 2017 the Turkish Pharmaceutical and Medical Device Authority ("Authority") published Guidelines on the 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 centers[413].

One of the more important clarifications in the Guidelines is the provision that states that in the event that a sales center 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 center. The Guidelines also state that any HCPs 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 center providing the support will be under the obligation to submit the information relating to said HCPs; both for the pre-approval and follow-up notifications for the conference.

[411] Section 5.12.b, ARTED Code
[412] Article 4(p) of the Regulation
[413] Companies that are engaged in the sales of medical devices in Turkey must be certified as an official sales center as per the Medical Device Sales, Advertisement and Promotion Regulation.

UK

MEDICAL DEVICES: ABHI

Updated: 18 August 2017

General update on the national code

ABHI carried out a complete transposition of the MTE Code—ABHI Code of Business Practice—which it published in May 2017. 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. ABHI has also included four new annexes relating to the MTE CVS and Disclosure of Education Grants on the MTE platform. ABHI was the first national association to transpose and publish the new MTE Code. The new ABHI Code comes into force as follows:

- 1 January 2017, the new complaints adjudication procedure came into force[414] (a relatively minor change).
- 1 January 2018, the new Code comes into force. By 31 December 2018 members must cease direct sponsorship of HCPs' attendance at Third Party Organised Educational Conferences.

Therefore, until 31 December 2017, the ABHI Code of March 2016 remains in force[415].

Procedural highlights

ABHI's Code includes an enforcement mechanism that is overseen by the Panel. It composed of individuals with a background in the industry and who have relevant expertise for assessing complaints under the ABHI Code[416]. ABHI has removed its Competition Law Guidelines from the Code, but they remain available on ABHI's website as a reference document[417].

Financial support of HCPs for attendance at Third Party Organised Educational Conferences

As mentioned above, until 31 December 2017, the ABHI Code of Business Practice of March 2016 remains in force (apart from the complaints procedure). As a result, until that date—where permitted under local laws, regulations and professional codes of conduct—members are still permitted to provide financial support to cover the cost of conference attendance by individual HCPs. As before, such financial support should be limited to the conference registration fee and reasonable travel, meals and accommodation costs relating to attendance at the event. However, as of 1 January, 2018 the entirety of the ABHI Code of May 2017 will come into force and replace the March 2016 Code.

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[414] Part 4: Complaints Procedure & Panel Constitution, ABHI Code of Business Practice (ABHI Code), May 2017
[415] ABHI Code, March 2016, available at: http://www.abhicodeofpractice.org.uk/multimedia/New%20Folder/ABHI%20CoBP%20-%20March%202016.pdf (last visited 30 August 2017)
[416] Part 4: Complaints Procedure & Panel Constitution, p 62, ABHI Code, May 2017
[417] Competition Law Compliance Guidelines, including Dos and Don'ts, available at: http://www.abhicodeofpractice.org.uk/cobp-documents.aspx

The ABHI Code of May 2017 is identical to the MedTech Europe Code except for the timing provisions. In particular, it is important to highlight that the timing of ABHI's transition period to phase out direct sponsorship of HCPs at Third Party Organised Educational Conferences is one year behind that of MedTech Europe. Under the ABHI May 2017 Code, the prohibition on direct sponsorship of individual HCPs will begin as of 1 January, 2019[418]. From that point on, Educational Grants become the only way to provide financial support to healthcare professionals to attend Third Party Organised Educational Conferences[419].

As the ABHI Code is identical to the MedTech Europe Code, it provides for the same definition of Educational Grants[420]. According to the ABHI Code[421], these include grants provided to support Healthcare Professional participation in Third Party Organised Educational Conferences. HCPs who benefit from this form of grant are selected by the receiver of the grant rather than the donor[422]. This means that grants can only be provided to legal entities, but never individuals and require a written Grant agreement, as well as any other required documentation. As always, conferences benefitting from an Educational Grant still need to comply with all the specific requirements as set out in the Code[423].

Arrangements with consultants

According to the ABHI Code, arrangements with consultants are permitted. It is appropriate to pay HCP reasonable compensation for performing these services. In addition, the ABHI Code clarifies what factors support the existence of a *bona fide* consulting agreement, some of which are the following[424]:

- Legitimate business purpose for the services is identified in advance
- Written agreement, signed by the parties must specify the services to be provided
- Compensation paid to HCP engaged as consultants must be of the fair market value for the services provided and must not be tied in any way to the value of medical devices which the consultants may use for their own practice
- Prior written notification should 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[425], etc.

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[426]. In early February 2017, the National Health Service (NHS) in England released a

[418] Part 2: Disclosure Guidelines, Preamble, ABHI Code, May 2017; see also Annex I: Direct Sponsorship of HCPs, p 73, ABHI Code, May 2017
[419] Introduction: Implementation & Transition Period, p 7, ABHI Code, May 2017
[420] Part 5: Glossary & Definitions, p 69, ABHI Code, May 2017
[421] Introduction: Implementation & Transition Period, p 7, ABHI Code, May 2017
[422] Part 1 Ch. 4 – Grants & Charitable Donations, p 25, ABHI Code, May 2017
[423] Part 1 Ch. 4 – Grants & Charitable Donations, p 25, ABHI Code, May 2017
[424] For the complete list see: Part 1 Ch. 6 – Arrangements with Consultants, p 31, ABHI Code, May 2017
[425] Pro-forma notification letter is available on the ABHI Code of Practice website: http://www.abhicodeofpractice.org.uk/cobp-documents.aspx (last visited 30 August 2017)
[426] Part 1 Ch. 1 – General Criteria for Events, p 11-12, ABHI Code, May 2017

guidance document[427], 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£[428]. ABHI's May 2017 Code was amended to take these spending limits into consideration[429].

Gifts

There is no maximal amount for gifts[430] or other specific legal requirements. However, the NHS has set the limit for these types of gifts at 6£[431]. 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[432].

In addition, ABHI Q&As provide further guidance on gifts[433].

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[434]. The first reporting period will be the calendar year of 2018 (1 January to 31 December)[435]. The ABHI Code includes two Annexes that provide further clarification on the disclosure guidelines, including an example of a methodology note.[436]

Misc.

The ABHI Code includes a section 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.[437] 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

[427] 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 August 2017)
[428] Managing Conflicts of Interest in the NHS, Hospitality, p 13
[429] Part 1 Ch. 1 – General Criteria for Events, FN 1, ABHI Code, May 2017
[430] Part 1 Ch. 9 – Educational Items & Gifts, p 38, ABHI Code, May 2017
[431] Managing Conflicts of Interest in the NHS, p 11
[432] Part 1 Ch. 9 – Educational Items & Gifts, p 38, FN 1, ABHI Code, May 2017
[433] Part 1 Ch. 9 – Educational Items & Gifts, Q&A 43-46, ABHI Code, May 2017
[434] Part 2: Disclosure Guidelines, p 49, ABHI Code, May 2017
[435] Part 2: Disclosure Guidelines, Q&A 7, p 48, ABHI Code, May 2017
[436] Part 6: Annexes, Annex II & III, p 74-75, ABHI Code, May 2017
[437] Part 3: Guidelines on advertisements and promotions addressed solely or primarily to HCPs, p 51, ABHI Code, May 2017

- Audio-cassettes, films, records, tapes, video recordings intended solely or primarily for release or use at HCP events[438]

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[439].

[438] Part 3: Guidelines on advertisements and promotions addressed solely or primarily to HCPs, p 52, ABHI Code, May 2017
[439] Part 1 Ch. 5 – Sponsored Posts, p 28, ABHI Code, May 2017

IN VITRO DIAGNOSTICS: BIVDA

Updated: 8 October 2017[440]

General Update on the national code

The BIVDA[441] Code of Conduct ("BIVDA Code") was first published in February 2008 and last updated in 2015. BIVDA has drafted and approved a new Code, bringing it in line with the MTE Code, which comes into force 1 January 2018

Procedural highlights

Currently, BIVDA"s Code is enforced through a complaints system, where complaints are directed to the Director General of BIVDA, who then forwards them to the BIVDA Executive Committee. The Committee investigates the complaint and issues a decision and/or recommendations. Appeals can be made to an independent council formed by BIVDA. BIVDA's current Code includes Competition Law guidelines.

Financial support of HCPs for attendance at Third Party Organised Educational Conferences

The current BIVDA Code[442] is a slightly amended version of the EDMA Code of Ethics. BIVDA Members may provide financial grants to cover conference costs and reasonable travel and lodging expenses of healthcare professionals (and medical students, residents, fellows, and others who are healthcare professionals in training) when the conference is primarily dedicated to promoting objective scientific and educational activities[443]. Such support should be consistent with the regulations of the country where the healthcare professional is licensed to practice. The conference organiser should be responsible for and control the selection of programme content, faculty, educational methods, and materials. The support by a member should be clearly stated in advance of, at the meeting and in the proceedings.

Arrangements with consultants

The BIVDA Code follows the EDMA Code in regards to arrangements with consultants. Therefore, BIVDA members may engage in bona fide consultancy arrangements with HCPs, provided they pay HCPs reasonable compensation for performing these services[444]. The bona fide nature of an arrangement may be assessed based in certain criteria such as:

- The Consulting arrangement should be in writing, signed by the parties and specify all services to be provided. It should also be consistent with the regulations of the country where the HCP is licensed to practice.

[440] This section has not been reviewed by the national association
[441] The British In Vitro Diagnostics Association (BIVDA) is the British industry association for companies in the in vitro diagnostics industry : https://www.bivda.co.uk/
[442] BIVDA Code of Conduct (BIVDA Code), approved in February 2008.
[443] BIVDA Code, Part A, Section II "Supporting Third Party Organised Educational Conferences"
[444] BIVDA Code, Part A, Section IV "Arrangements with consultants"

- Compensation should be independent of the value of in vitro diagnostic devices which consultants may use for their own practice; it should be paid based on services actually provided and in accordance with applicable tax and other legal requirements. Members may pay for reasonable expenses incurred by consultants in carrying out the consulting agreement.
- The arrangement should have a legitimate purpose
- The selection of the consultant should be based on the HCP qualifications and expertise on the particular issue.
- The venue should be appropriate to the subject matter of the consultation. Member-sponsored hospitality taking place in conjunction with a consultant meeting should be modest in value and should be subordinate in time and focus to the primary purpose of the meeting.
- When a BIVDA member contracts with an HCP acting as consultant for research services, there should be a written research protocol and all required consents and approvals should be obtained.

Meals, travel and accommodation expenses

The BIVDA Code does not differ from the EDMA Code regarding accommodation, meals and travel expenses. BIVDA Members may provide financial support to the conference organiser in the form of meals and hospitality for programme attendees. Any meals and hospitality should be modest in value and should be subordinate in time and focus to the purpose of the conference. Members may provide financial grants to reasonable travel and lodging expenses of HCPs[445].

Gifts

As in previous sections, the BIVDA Code aligns with the EDMA Code. BIVDA Members occasionally may provide gifts to HCPs, provided they are modest in value and in accordance with the regulations of the country where the HCP is licensed to practice. Gifts should benefit patients or take a genuine educational form. BIVDA members may occasionally give HCPs branded promotional items of minimal value related to the HCP's work or for the benefit of patients. Gifts should not be given in the form of cash or cash equivalents[446].

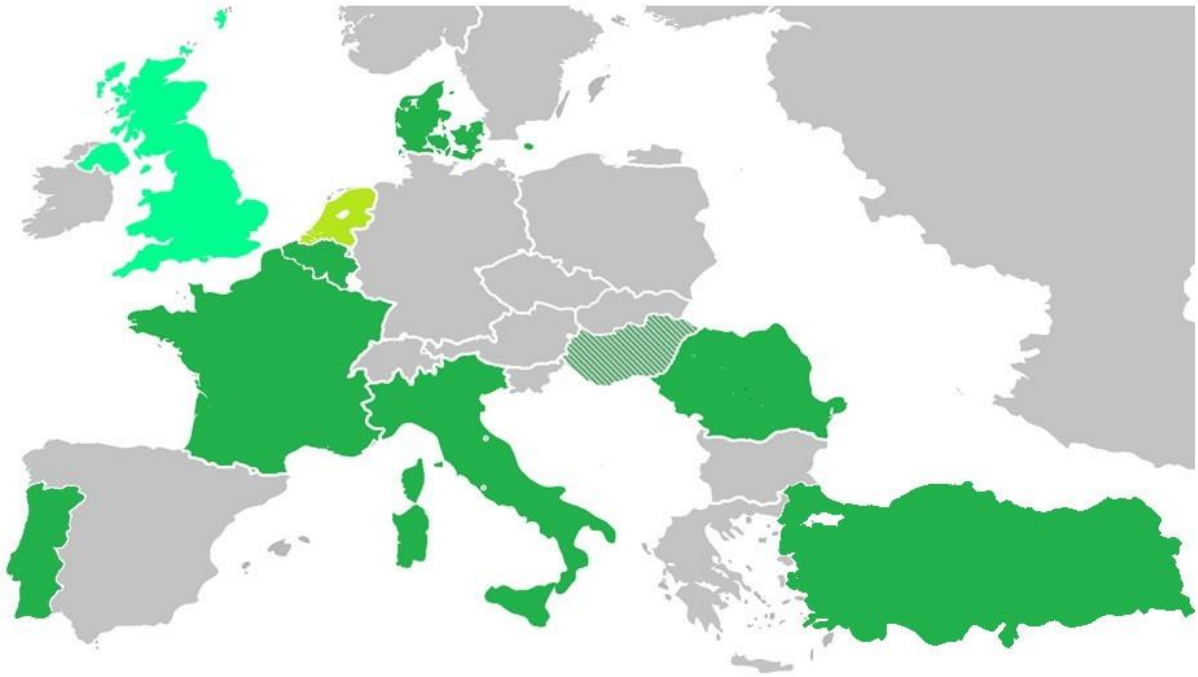
Transparency

BIVDA has elected to use the MedTech Europe platform for grant disclosures.

[445] BIVDA Code, Part A, Section II
[446] BIVDA Code, Part A, Section V

Annex: Maps and tables

Map 1: Overview; transparency systems in Europe for the MedTech industry



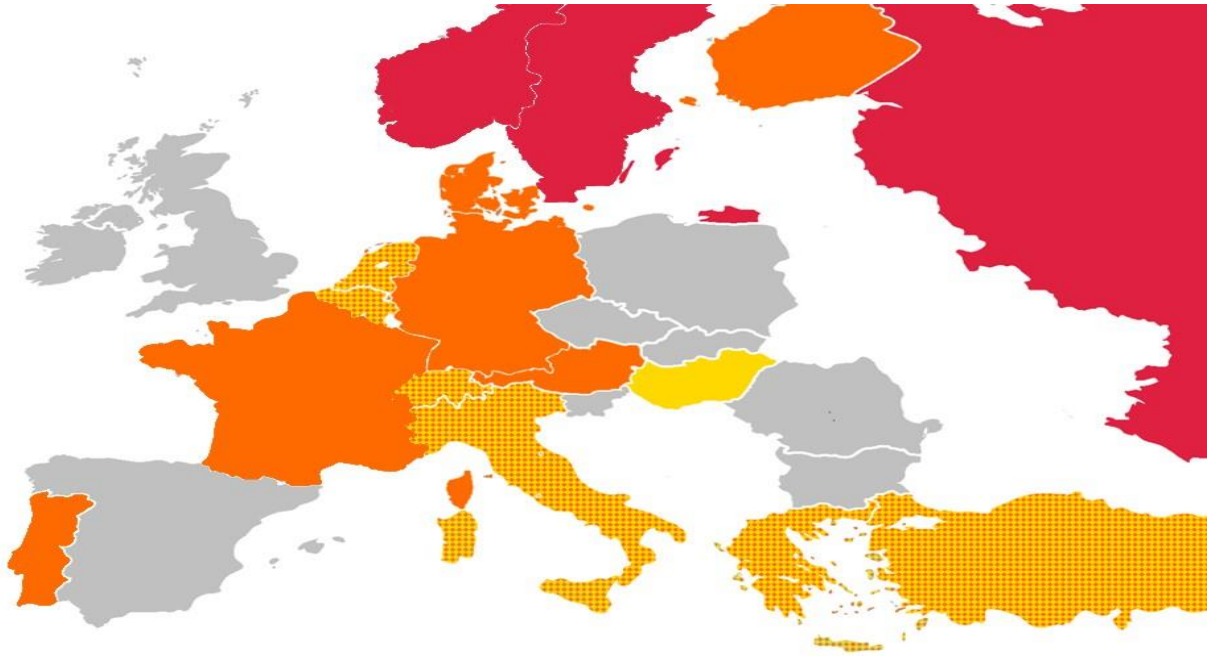
Countries with a transparency system established by Law: Belgium, Denmark, France, Italy, Portugal, Romania & Turkey

Hungary: Only applicable to Medical Aids, please see relevant section

Countries with a transparency system established by self-regulation: Netherlands

Countries where a transparency system is going to be implemented in the near future or where discussions are advanced: United Kingdom

Map 2: Legal limits to direct sponsorship of HCPs to attend Third Party Organised Educational Conferences[447]



Category 1: Countries in which direct sponsorship of HCPs to attend Third Party Organised Educational Conferences is forbidden

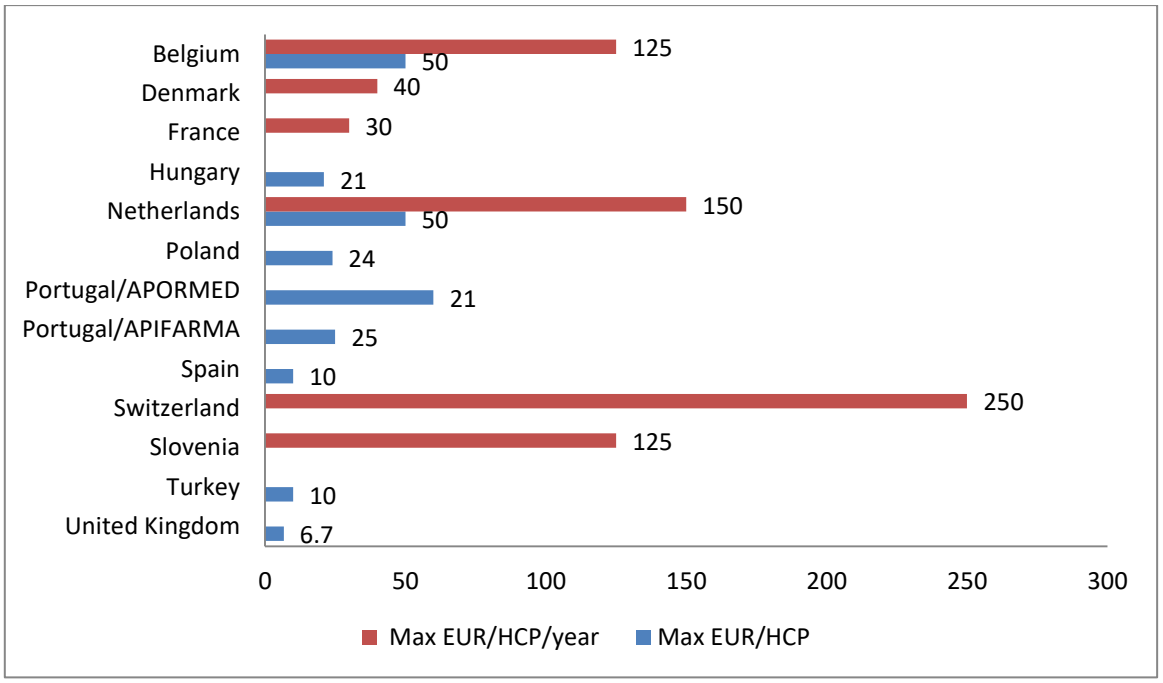
Category 2: Countries in which direct sponsorship of HCPs to attend Third Party Organised Educational Conferences requires any kind of previous employer approval, or where the invitation must be directed to the employer.

Category 3: Countries in which direct sponsorship of HCPs to attend Third Party Organised Educational Conferences is limited in any way (limits to the costs to be paid to the HCP, special rules for events taking place abroad, etc.).

Category 4: Countries in which direct sponsorship of HCPs to attend Third Party Organised Educational Conferences falls within categories 2 and 3.

[447] Please note that Sweden and Norway have banned direct sponsorship via a stakeholder agreement

Table 1: National limits* for gifts: 2017



*Note that some of the limits are approximate based on current exchange rate of certain non-EURO currencies (please refer to the chapter of the relevant country for more information).

Hungary: The value of the gift should not exceed 5% of the official minimum wage. The current value is calculates based on the gross minimum monthly wage in 2017: 127.500 HUF, approximately 412 EUR.

Slovenia: This amount is set by law and applies to gifts given to individuals working in the public sector.

About MedTech Europe

MedTech Europe is the only European trade association representing the medical technology industry from diagnosis to cure. We represent In-Vitro Diagnostics and Medical Devices manufacturers operating in Europe.
MedTech Europe promotes a balanced policy environment that helps the medical technology industry meet Europe's growing healthcare needs and expectations. We also promote the value of our industry and how medical technologies can help save and improve lives, and help support more sustainable healthcare systems.

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