

**SPECTARIS Code of Conduct:
Recommendations for
collaborations in the healthcare
industry**

September 2017

Contents

Preamble: Starting situation and framework conditions	4
Strengthening ethical business practices in the health sector	6
Goals and basic principles of the code	6
Interpretation of the SPECTARIS Code of Conduct	8
Application of the SPECTARIS Code of Conduct	8
Timeframe to start implementing the recommendations	8
PART 1: Regulations for interactions between medical professionals and healthcare institutions	9
Chapter 1: General criteria for events	9
1. Event programme	9
2. Event location	10
3. Guests	10
4. Appropriate hospitality	11
5. Travel costs	11
6. Transparency	11
Chapter 2: External training, further education, and continuing development events organised by third parties	13
1. Externally organised training, further education, and continuing development conferences	13
2. Application training organised by third parties	14
3. Transition phase: Direct financial support for medical professionals to take part in further educational events externally organised by third parties	14
Chapter 3: Internal company events	15
1. General principles	15
2. Product and application education and training, further education, and continuing development events	15
3. Sales, marketing, and other business meetings	15
Chapter 4: Grants and donations for charitable purposes	16
1. General principles	16
2. Donations for charitable purposes	17
3. Educational grants	17
a. Grants for external further education events	18
b. Scholarships and fellowship programmes	19
c. Grants for awareness campaigns	19
4. Research grants	19
Chapter 5: Agreements with consultants	20
1. General principles	20

2. Criteria for consulting agreements	20
3. Compensation and usual market value	21
4. Disclosure and transparency	21
Chapter 6: Research	23
1. Research commissioned by member companies	23
2. Product evaluation by the member company after launching the product	23
3. Research studies commissioned by third parties	24
Chapter 7: Licence fees	25
Chapter 8: Material for professional further education and gifts	26
Chapter 9: Demonstration products and samples	27
1. General principles	27
2. Demonstration products	27
3. Samples	28
PART 2: Disclosure guidelines	29
Foreword	29
Chapter 1: Applicability of these guidelines	29
1. Scope	29
2. Applicability of these disclosure guidelines	30
3. Applicability for non-member companies	30
Chapter 2: Obligation to disclose	30
1. General obligation	30
2. Collective disclosure	30
3. Optional object specification	31
4. Methodology	31
Chapter 3: Type of disclosure	31
1. Reporting period	31
2. Time of disclosure	31
3. Time of publication	31
4. Presentation and language of the disclosure	32
5. Disclosure platform	32
6. Maintaining and adapting disclosures	32
7. Inquiries regarding submitted disclosures	32
PART 3: Glossary and definitions	32

Preamble: Starting situation and framework conditions

With the recommendations at hand, the industry association SPECTARIS e.V. underscores the necessity of transparent, legally compliant collaborations between medical technology manufacturers and home-care providers and healthcare professionals, medical facilities, as well as healthcare institutions and their employees. The recommendations made in the SPECTARIS Code of Conduct correspond exactly with the regulations of parts 1, 2, and 4 of the MedTechEurope Code of Ethical Business Practice as presented in the German translation of the December 2016 version. The scope of application of the recommendations therefore relates to both the national and the international context.

In addition, medical technology companies are advised to inform themselves about the respectively applicable laws concerning the topic of “Collaborations in the Healthcare Sector”. Aside from the relevant national laws, companies should also take into account the applicable laws of the states and countries in which they have conducted or are conducting business activities or from which their business partner originates.

It should be noted that, in addition to legal regulations, many states and countries also have voluntary codices in place that authorities can consult when interpreting the laws.

In Germany, the following laws in particular should be observed:

1. Criminal code
2. Social Codes, especially Social Code Book 5
3. Professional codes and regulations for health professions
4. Pharmaceutical advertising law
5. European Medical Device Regulation (MDR) and the resulting legal provisions
6. Law Against Unfair Competition
7. Public service law

and the administration of justice based on these.

Health is a person’s most valuable possession. Medical technology companies in Germany make a considerable contribution to the development of new products and treatment methods and thereby constitute an essential requirement for medical progress and the continuous improvement of patient treatment.

The industry, medical professionals, and medical institutions depend on close cooperation to improve healthcare for the benefit of the patient.

In this context, research and development as well as the production and distribution of medical technology products are a special responsibility that manufacturers, distributors, employees in medical facilities, and other service providers have to bear. The industry association SPECTARIS e.V. and its member companies are aware of this responsibility and are putting it into practice by actively promoting and complying with the following recommendations.

Here, the key guidelines of the principle of separation, transparency, documentation, and appropriateness as well as the principle of external perception are of crucial importance.

Berlin, September 2017

INTRODUCTION

Strengthening ethical business practices in the healthcare sector

SPECTARIS represents medical technology companies in Germany. In addition to serving as an industry representative and promoting industry connections and development, our goal is to achieve a balanced regulatory environment that supports the medical technology industry in fulfilling the rising demands of the healthcare sector and the increasing ethical expectations of its business partners.

SPECTARIS recognises that compliance with valid laws and guidelines as well as with ethical standards constitutes a crucial step towards achieving the above-mentioned goals. At the same time, this can positively influence the reputation and success of medical technology companies.

The code recommends reasonable minimum requirements relating to the various fields of activity in which SPECTARIS members operate. The code is not intended to replace or supersede national laws, guidelines, or professional codes that set stringent requirements for members. All members should independently verify that their activities comply with all applicable national laws, guidelines, and professional codes.

Furthermore, member companies should be aware that they could be held liable for the activities of third parties who contact medical professionals or healthcare institutions with regard to the distribution, advertising measures, or other activities connected to the products of member companies. When cooperating with third parties (for example, consultants, traders, sales representatives, brokers, commercial agents, independent distributors, and others), it is therefore recommended to contractually obligate them to consult this code and the regulations it contains as a guideline on conduct.

Goals and basic principles of the code

The cooperation between SPECTARIS members and medical professionals as well as healthcare institutions is important for achieving the goal of offering more people access to safe, innovative and reliable technologies, and associated services. Examples of these include:

- **Development and advancement of medical technologies**

Developing innovative medical devices, technologies, and in-vitro diagnostics as well as improving existing products requires collaboration between member companies, medical professionals, and healthcare institutions.

- **Safe and sustainable use of medical products**

To guarantee the safe and effective use of medical products and associated services,

member companies must offer medical professionals and healthcare institutions appropriate instruction, training, further education, courses, study, services, and technical support.

- **Research as well as training, further education, and continuing development courses**
The support provided by medical research, as well as training, further education, and continuing development courses offered by member companies help medical professionals improve their clinical skills. These also increase patient safety and allow for better access to new technologies and/or associated services.

In any form of such a collaboration, member companies must take into account that medical professionals make independent decisions on treatments. Furthermore, the type of collaboration must preserve the integrity of the industry. To achieve this goal, the code offers instructions on how member companies should work together with medical professionals and healthcare institutions. These are based on the following fundamental principles:

- **Principle of external perception:**
Member companies should always take the public reputation and perception of the medical technology industry into account when working with medical professionals and healthcare institutions.
- **Principle of separation:**
Collaborations between the medical technology industry and medical professionals/healthcare institutions may not be misused to influence purchasing decisions by granting inappropriate or impermissible benefits or to make these dependent on the purchase, prescription, or recommendation of member company products.
- **Principle of transparency:**
Collaborations between the medical technology and diagnostics industry and medical professionals/healthcare institutions must be transparent and comply with national laws, guidelines, or professional codes. Even in countries without any specific regulations in place, member companies should provide an appropriate level of transparency by contacting the hospital administration, the superior of the medical professional, or another responsible authority in advance and providing them with complete, written information on the purpose and scope of the cooperation.
- **Principle of appropriateness:**
If a member company commissions medical professionals to carry out a service on behalf of the member company, the member company must offer appropriate compensation that corresponds with the usual market value of the services performed by the medical professional.

- **Principle of documentation**

All such services and return services should be designed and documented in writing in a way that ensures verifiability and transparency at all times. Among other things, a written agreement must include the scope and purpose of the cooperation, the reciprocated services which have been or will be performed and are to be substantiated, as well as the method of reimbursement and financial compensation. The considerations upon which the decisions of appropriateness were based should also be documented. Proof of performance of the services must be provided. The member company should store the complete documentation, including the agreement, reports, assessments, invoices, etc. for an appropriate time period in order to verify the materiality of the services as well as the legitimacy of the compensation paid.

Interpretation of the SPECTARIS Code of Conduct

The most important terms relating to this Code of Conduct are explained in the glossary.

Every sentence that starts with the words “including”, “among others”, “especially”, or similar expressions should be interpreted as exemplary and should not restrict the meaning of the words preceding these terms.

Application of the SPECTARIS Code of Conduct

Subject to the relevant legal situation, it is recommended that members of the SPECTARIS trade association for medical technology follow the *SPECTARIS Code of Conduct: Recommendations for collaborations in the healthcare sector*.

SPECTARIS is consciously forgoing the use of a procedural framework with automatic complaints and sanctioning, as envisaged by the MedTech Europe Code of Ethical Business Practice, and, in this respect, also does not function as an arbitration board.

Disputes or differences regarding the interpretation of the code will generally be solved on a national level among those involved and without including SPECTARIS in the process.

[The Conference Vetting System](#) is an independently managed system which monitors compliance with the code through external training, further education, and continuing development events organised by third parties (see [Glossary](#)).

The code will be examined if needed and adjusted as necessary.

Timeframe to start implementing the recommendations

These recommendations fully replace the previous SPECTARIS recommendations for collaborations in the healthcare sector (SPECTARIS Code of Conduct: Recommendations for Collaborations in the Healthcare Sector) as of 1 January 2018.

So-called direct sponsorship includes direct support for medical professionals to participate in external training, further education, and continuing development events organised by third parties.

Due to current political and legal developments on a national and international scale, SPECTARIS recommends that its member companies avoid directly sponsoring individual medical professionals by 1 January 2020 at the latest. An exception to this is application training organised by third parties or a medical professional's participation as a speaker at a satellite symposium as part of a consulting agreement. This means that, according to the code's recommendations, direct support of an individual medical professional's participation in external development events should be avoided.

SPECTARIS therefore recommends that, as of 1 January 2020, its member companies only provide financial or material support for external further education events by means of educational grants or other stipends in accordance with the regulations in [Chapter 2: External training, further education, and development events organised by third parties](#) and [Chapter 4: Grants and donations for charitable purposes](#).

PART 1: Regulations for interactions between medical professionals and healthcare institutions

Chapter 1: General criteria for events

Member companies can invite medical professionals to internal company events (see [Glossary](#)) as well as grant subsidies for external further education events organised by third parties. The principles and criteria illustrated in *Chapter 1* apply to all events (see [Glossary](#)) that member companies have in any way supported, regardless of who is hosting the event.

1. Event programme

The event programme must correspond with the specialisation or practice of the medical professionals participating in the event, and the programme should be sufficiently scientifically relevant to justify the medical professional's participation. The organising third party carries the responsibility of and controls the programme at such events.

A member company should neither host events that include social activities, sports and/or leisure activities, or other types of entertainment (see [Glossary](#)) nor support these elements as parts of external training, further education, and continuing development events if the participants do not bear the costs of such activities themselves. At external further education events, entertainment should only take place outside of the training, further education, and continuing development programme and should be paid for separately by the medical professionals. The entertainment offer should not affect the scientific programme and should by no means overlap with the scientific session. Entertainment should not constitute the main attraction of an external development event, as the scientific character could otherwise be denied.

2. Event location

The event location should not be the main attraction of the event. Member companies should always consider the following aspects when choosing an event location:

- The potential negative public perception of the event location: The event location should not give the impression of being luxurious or touristy, and it should not be a holiday location or a venue for entertainment events.
- The event location should be centrally located in relation to the places of residence of the invited participants.
- Easy accessibility should be ensured for all participants.
- The event location should be situated in a city or near a city that is known as a renowned scientific or business centre and is suitable for an event for exchanging ideas and knowledge.
- Member companies should also take into consideration the time of year at which the event is set to take place. The selected time should be chosen in such a way that it does not coincide with the local tourist season.¹

3. Guests

Member companies may not reimburse expenses for food, travel, accommodation, or other expenses for guests (see [Glossary](#)) of the medical professionals or cover the costs of these, nor may they cover any costs for other people that have no professional interest in the information presented at the event.

¹ For example, for European and international events this includes ski resorts in the time period from 20 December to 31 March.

4. Reasonable hospitality

The costs for reasonable hospitality for the medical professionals that attend internal company events and external training, further education, and continuing development events organised by third parties can be covered if the following requirements are met. However, the offered hospitality should always be subordinate to the duration and purpose of the event. Member companies should take due account of the provisions on hospitality in the country in which the medical professional works, as well as the provisions in the country in which the event is taking place.

The code aims to secure a balance between an appropriate and professional treatment of medical professionals by member companies. Member companies should avoid giving the impression that hospitality is used by them as a means of encouraging medical professionals to purchase, prescribe, or recommend products of the member companies.

All member companies must therefore carefully evaluate what is considered “appropriate” in a certain situation, while also taking regional differences into consideration. The normal standard for the respective place, which corresponds with national laws, guidelines, and professional codes, should be considered “appropriate”. The term “hospitality” comprises food and accommodation, although it is important to differentiate between permitted “hospitality” and impermissible entertainment.

Member companies should not pay for medical professionals to stay in luxury hotels or reimburse such costs. In general, accommodation at the conference hotel is permissible, provided that the requirements of the code are met. However, accommodation costs and/or other repayable expenses accrued by the medical professionals should not extend beyond the official duration of the event.

5. Travel costs

Member companies should only pay for or reimburse travel costs that are appropriate and were actually accrued. However, the medical professionals’ arrival and departure should not take place outside of the official time period of the event.

For air travel, this principally means that member companies should only pay for or reimburse economy or standard tickets, unless the flight time amounts to more than 5 hours, including connecting flights. In this case, a business class ticket may be considered. “First class” should never be regarded as appropriate.

6. Transparency

Member companies are urgently advised to fully comply with the respectively valid laws, guidelines, and professional codes to ensure disclosure or approval of financial support. Appropriate transparency should, at a minimum, guarantee that the employer has received notification before the event (see [Glossary](#)).

In accordance with this code, member companies can provide financial or material support (e.g. products made by member companies) for external further education events. This can comprise the following types of events:

- External further education conferences
- External application training

Chapter 2: External training, further education, and continuing development events organised by third parties

Member companies are advised to only grant financial or material support (e.g. products made by member companies) to external further education events in accordance with the guidelines of this Code of Conduct and under consideration of the respectively applicable legal regulations. These events include:

- external training, further education, and continuing development events organised by third parties and
- external product or application training organised by third parties.

1. Externally organised training, further education, and continuing development conferences

Member companies should only provide financial and/or material support to further education conferences organised externally by third parties (see *Glossary*) if:

- this complies with the requirements set out in *Chapter 1: General criteria for events* and
- insofar as required, permission has been granted by the Conference Vetting System (see *Glossary*).²
- this is permissible according to national law, guidelines, and professional codes.

This can be done by means of grants or other forms of funding. An evaluation by the Conference Vetting System is recommended, e.g.:

a. Educational grants

See [Chapter 4: Grants and donations for charitable purposes for further information](#).

b. Marketing activities

Member companies can purchase conference packages that include marketing services, e.g., advertising space and stand space for exhibiting products and services. Companies should ensure that the public image conveyed through the marketing activities is always perceived as professional. It may never bring disrepute to the medical technology industry or damage the trust in the medical technology industry.

c. Satellite symposia

Member companies can purchase packages for satellite symposia that form part of training, further education, and continuing development conferences and present topics that are compatible with the general content of the external further education conferences. Member

² Information on the scope of the Conference Vetting System is available at: <http://www.ethicalmedtech.eu>.

companies are responsible for the content of these satellite symposia and for the selection of speakers.

2. Application training organised by third parties

Member companies can support application training organised by third parties, either through educational grants (in accordance with [Chapter 4: Grants and donations for charitable purposes](#)) or by providing direct financial support for individual medical professionals to participate, in accordance with the following basic principles:

- Financial support should meet the criteria set out in [Chapter 1: General criteria for events](#). According to these, member companies can generally pay for travel costs, hospitality, and registration fees.
- In case of any concerns, application training organised by third parties should also obtain approval through the Conference Vetting System (see [Glossary](#)).
- When providing financial support for application training, member companies must take into account the local regulations of the country in which the medical professional practices their profession and the country in which the event is taking place.

3. Transition phase: Direct financial support for medical professionals to take part in further education events organised externally by third parties

Insofar as the law and jurisdiction still allows member companies to financially support individual medical professionals by covering the costs of their participation fee for external further education events organised by third parties, this remains possible. However, member companies are urgently advised to refrain from doing so as of 1 January 2020. Such financial support should be provided in accordance with the following requirements:

- Financial support should meet the criteria set out in *Chapter 1: General criteria for events*. Member companies can also cover the costs of the registration fee.
- If necessary, the further education event organised by third parties should have been approved by the Conference Vetting System (see *Glossary*).
- If providing financial support for external further education events, member companies are urgently advised to take into account the relevant regulations of the country in which the medical professionals practice their profession and in which the event is taking place.

Chapter 3: Internal company events

1. General principles

Member companies can invite medical professionals to internal company events. As defined in the [glossary](#), these events comprise:

- Product and application training as well as training, further education, and continuing development events, sales, marketing, and other business meetings
- Internal company events should fulfil the criteria set out in *Chapter 1: General criteria for events*.

If a legitimate business purpose exists, internal company events can also take place at the member company's production site or at healthcare institutions that are used by member companies as reference centres.

2. Product and application education and training, further education, and continuing development events

Member companies can conduct product and application training as well as other training, further education, and continuing development events for suitable medical professionals to ensure the safe and effective use of medical technologies, therapies, and/or services.

Member companies should ensure that the product and application training as well as further education events are run by specialists with the relevant expertise.

3. Sales, marketing, and other business meetings

Member companies can organise sales, marketing, and other business meetings (see [Glossary](#)) to discuss the functions and advantages of products and associated services, negotiate contracts, or determine sales conditions.

In addition to the basic principles from *Chapter 3, Section 1*, the following strict requirements must be fulfilled during sales, marketing, and other business meetings:

- Meetings should generally take place at or near the medical professional's workplace;
- Travel and accommodation costs for the medical professional should not be reimbursed unless the meeting involves presentations of non-transportable devices.

Chapter 4: Grants and donations for charitable purposes

1. General principles

- a. Grants and donations for charitable purposes (see [Glossary](#)) must not be contingent on past, current, or future purchases, recommendations, prescriptions, applications, deliveries, or procurement of products or services offered by the member company. It is important that the member company's support of charitable programmes and activities is not viewed as a price concession, reward for preferred customers, or as an incentive to purchase, rent, recommend, prescribe, use, deliver, or procure products or services offered by the member company. Grants to facilities or institutions should ideally only be made if a donation receipt is provided.
- b. A member company should not give grants and donations for charitable purposes to individual medical professionals. Grants and charitable donations must be transferred directly to recognised facilities, organisations, or institutions. Charitable donations should not be granted based on the request of a medical professional unless the medical professional is an employee or person responsible representative of the respective facility, organisation, or institution, or a department at one of these, and submits a written request on behalf of the respective facility, organisation, or institution.
- c. Payment (or provision of other types of support) in the form of a grant or charitable donation must always be issued in the name of the supported facility, organisation, or institution and paid directly to them. Grants and charitable donations may not be issued in the name of an individual medical professional, and the member company must always be identifiable as the provider.
- d. The receipt and use of grants and charitable donations must always be lawful for the recipient in accordance with the applicable laws, guidelines, and professional codes.
- e. Member companies should introduce an independent decision-making/evaluation process designed to detect and prevent risks of bribery and corruption that can be associated with the provision of grants and charitable purposes to a potential beneficiary. This process includes a documented evaluation of the possible risks and the relevant information on the intended beneficiary facility, organisation, or institution and should be carried out before granting the service.
- f. All grants and charitable donations should be documented accordingly by the member company. Furthermore, grants and charitable donations should only be made upon receipt of a written application from the facility, organisation, or institution making the request or on the basis of a documented initiative on the part of the member company. The documentation must contain sufficient information to enable an objective evaluation of the request by the member company. Grants and charitable donations should only be granted once both parties have signed a written agreement detailing all conditions.
- g. This section of the code (*Chapter 4: Grants and donations for charitable purposes*) does not apply to the legitimate practice of member companies offering reasonable discounts, additional product and/or service offers, including free offers, or other comparable pricing mechanisms

(added value) which are common in competitive and transparent centralised purchasing agreements, for example in tenders.

2. Donations for charitable purposes

Member companies can make donations for charitable purposes without a specified purpose. In this context, “without a specified purpose” means that member companies do not control the ultimate use of the donation (or another form of support), aside from the general restriction that the donation (or other form of support) must be used for charitable and/or philanthropic purposes.

Such donations should only be made to charitable institutions or other non-profit organisations whose verifiable main purpose is to support and carry out charitable and/or philanthropic activities. These donations must always be made in accordance with the general principles set out in [Chapter 4: Grants and donations for charitable or other philanthropic purposes](#). Companies should request a donation receipt from the recipient, for tax-law purposes among other reasons.

In the case of a verified financial emergency (see [Glossary](#)), charitable donations may be made for specific purposes to non-profit hospitals, insofar as the donations exclusively serve the good of the patients, are restricted in value, or are expressly permitted by the applicable laws, guidelines, and professional codes.³

This section of the code (*Chapter 4: Grants and donations for charitable purposes*) does not apply to member companies’ legitimate commercial activity of renting stand spaces at external training, further education, and continuing education events and/or at a conference or event organised by a charity or a philanthropic institution. These activities are considered to be part of the general marketing activities carried out by member companies.

However, member companies should always take the appropriateness of the location, the event venue, and the general focus of these events into account to avoid a potential negative impact on the industry’s reputation.

3. Educational grants

Member companies may offer educational grants for a specified purpose (see [Glossary](#)) to promote medical training, further education, and continuing development. The intended use must be indicated in the educational grant agreement. A member company must also ensure that the educational grant contract with the beneficiary organisation contains rights which make it possible for the member company to guarantee that the grant is actually used for the agreed purpose.

³ According to the code, a hospital’s main purpose is to provide medical care to the general public and not to fulfil a charitable or philanthropic purpose. For this reason, a donation in the sense of the code can only be given to a hospital in case of a financial emergency and not to support the general hospital operations.

Member companies should detail all educational grants in accordance with the transparency guidelines of the code.⁴

Member companies may offer educational grants for the following purposes (not a conclusive list):

a. Grants for external further education events

All external further education events that a member company supports by means of providing an educational grant to a healthcare institution should:

- comply with the requirements set out in [Chapter 1: General criteria for events](#); and
- if necessary, have obtained approval from the Conference Vetting System (see [Glossary](#)).

1) Supporting the participation of medical professionals in external further education events organised by third parties:

If the educational grant serves the purpose of supporting the participation of a medical professional in an external further education event, the healthcare institution that is the intended beneficiary of the grant is exclusively responsible for selecting the participants. This must be expressly stated in a written funding agreement.

2) Grants for running external further education events:

If the organiser of the external further education event that is to receive an educational grant is a healthcare institution, then this institution is exclusively responsible for:

- the programme contents;
- the selection of speakers; and
- if relevant, compensation for the speakers.

Member companies may not influence the contents of an external further education programme or the selection of speakers (see [Glossary](#)). This will be set down in a written funding agreement. If member companies are expressly asked to do so, they can recommend individual speakers or offer comments on the programme.

⁴ The Transparency Disclosure Guidelines can be found in Part 2.

b. Scholarships and fellowship programmes

Member companies can provide educational grants for a specific purpose in the form of grants for scholarships and fellowship programmes (see [Glossary](#)) in order to support the training, further education, and continuing development of medical professionals. Only healthcare institutions that train medical professionals should be able to apply for these educational grants. Educational grants for scholarships and fellowship programmes may not be granted based on the request of individual medical professionals, nor should the member company exert any influence on the selection of the medical professionals that will benefit from the educational grants; this should be set down in a written funding agreement between the member company and the beneficiary healthcare institution.

c. Grants for awareness campaigns

Member companies can also provide grants for a specified purpose to healthcare institutions in order to provide general information, promote awareness of health topics, and/or educate patients, caregivers, or the general population on relevant health topics or diseases within the therapy area in which the member company operates.

4. Research grants

Insofar as permitted by national laws, guidelines, and professional codes, member companies can offer research grants for specified purposes (see [Glossary](#)) for clearly defined research studies initiated by third parties as part of clinical or non-clinical research programmes within the areas in which the member companies operate. The research grants can comprise material or financial support for lawful, study-related, verifiable expenses or services and/or contain an appropriate number of free single-use and/or reusable products for a period limited to the duration of the research work.

In the case of research studies initiated by third parties, member companies offering research grants should not exert any influence on the research work. However, to guarantee that the research grants are used for the specified purpose, they should define the planned research area and intended purpose of the grant in writing. In addition, the grant agreement should provide a written statement to make sure that the funds are exclusively used for the approved research purpose. To document the specified use of the provided funds, the member company should request a copy of the research protocol, the approval of the ethics committee and/or responsible authorities if required, as well as a copy of the final report of the study for its records.

Research grant contracts should ensure that potential undesired results are documented accordingly. The respective research grant as well as the member company offering it and the beneficiary third party should be disclosed in full in all written and oral presentations of the studies.

Instructions on conducting research work commissioned by member companies can be found in [Chapter 6: Research: Research work commissioned by member companies](#).

Chapter 5: Agreements with consultants

1. General principles

Member companies can hire medical professionals for consulting and other services, e.g. research work, participation in advisory committees, presentations at internal company events, and product development. Member companies should pay medical professionals appropriate compensation for their services. The decision-making criteria for evaluating appropriateness should be documented. The consulting agreement should always comply with the national laws, guidelines, and professional codes of the country in which the medical professional is authorised to work or practices their profession, as well as fulfilling the applicable professional codes of the respective country.

The basic principles detailed in this chapter apply to all consulting agreements between medical professionals and member companies, even if the consulting medical professional refuses compensation for their services and performs these free of charge.

Consulting agreements should never be contingent on the future consultant's past, current, or potential future purchases, rentals, recommendations, prescriptions, uses, deliveries, or acquisitions of products or services offered by the member company.

2. Criteria for consulting agreements

Agreements concerning expert consulting or other services should, in addition to the general principles listed above, always meet the following criteria:

- a. Consulting agreements should only be made if a member company has determined a legitimate business need for this service in advance.

- b. A member company should only hire as many consultants as is appropriate and required for its actual needs.

The selection of consultants should primarily be based on criteria such as the member company's actual needs, as well as the consultant's qualifications, expertise, and experience in addressing the determined needs. The value and scope of the business relationship with the potential consultant or the healthcare institution at which they are employed do not constitute relevant criteria.

- c. Consulting agreements with medical professionals should always be made in writing. The agreement must be signed by both parties before the services begin and include the type of services to be performed and the payment basis for these services.

d. The consultant's employment should be designed in such a way that it does not present an incentive for them to purchase, rent, recommend, prescribe, use, deliver, or acquire the products and services of the member company.

e. Payment for the provided services should above all be appropriate and correspond with the usual market value of the performed services.

f. Member companies are urgently advised to store the documentation on these services and the respective results as well as documents for the use of these services.

g. Regarding the location of the service provision and other agreements (e.g. accommodation, travel costs, etc.) for meetings between the member company with consultants, the event regulations detailed in [Chapter 1: General criteria for events](#) should be taken into account.

3. Compensation and usual market value

The compensation that medical professionals receive as consultants to member companies must correspond with the usual market value of the services provided. It may not in any way be tied to the products or services which the consultant may purchase, rent, recommend, prescribe, deliver, or acquire in the context of their main occupation or which healthcare institutions purchase, rent, recommend, prescribe, deliver, or acquire to carry out their professional activities.

All compensation for services provided must be paid in accordance with applicable tax law and other legal regulations. Member companies can bear the costs of appropriate expenses that consultants may have accrued while performing the agreed services. These include reasonable costs for travel, food, and accommodation that the consultants had to pay over the course of meetings with or on behalf of the member company. The expenses tied to the provision of services for which the consultant can be reimbursed as well as the basis for invoicing by the member company must be made clear in the written consulting agreement.

4. Disclosure and transparency

Member companies should ensure that they fully comply with all applicable laws, guidelines, and professional codes regarding publication, disclosure, or approval in connection with employing medical professionals as consultants for member companies. All the necessary approvals and permissions must be obtained, including from the hospital administration, the medical professional's superior, or another responsible authority. Should no corresponding national regulations exist, the member company should nonetheless ensure appropriate transparency and demand a respective message be sent to the employer that details the purpose and scope of the advisory activities.

In addition, it is recommended that the consultant be obligated towards the member company to list their status as a consultant for the member company as well as their contribution to the research for scientific publications or in creating publication material in all publications or presentations.

These recommendations and the documentation particularly serve the purpose of enabling the member company to present proof of ethical business practices in case of investigations by a public prosecutor.

Chapter 6: Research

1. Research commissioned by member companies

In case of a justified need to collect data before or after the launch of a product, member companies can commission, conduct, manage, and finance scientifically relevant research work. A justified need to collect data includes:

- medical purposes, including patient safety;
- research and development;
- scientific purposes (e.g., performance indicators, comparison of objective scientific parameters);
- meeting regulatory requirements, including market observation and monitoring, as well as evaluating clinical effectiveness and security after launching a product;
- compensation regulations, health economics matters, cost efficiency, and results that are relevant for health-related evaluations and decisions on reimbursement of costs.

If a member company is using a medical professional as a consultant, for example to run a study on behalf of a member company (i.e. as a principal investigator), the member company should ensure that these consulting activities fulfil all criteria listed in [Chapter 5: Agreements with consultants](#).

In accordance with the documentation principle, all agreements on conducting research work must be made in writing. This includes a written research protocol and a written work programme, as well all permits, approvals, and authorisations required before starting the study. Member companies should ensure that their research activities comply with all valid national laws, guidelines, and professional codes, as well as the relevant guidelines for good clinical practice, if applicable.

According to the basic principles in the [Introduction: Goals and basic principles of the code](#), member companies should also ensure appropriate transparency with regard to their research activities and results in clinical studies. This refers to the appropriate disclosure of information on clinical studies by member companies, for example in external public registers and specialist publications.

If member companies employ third parties for research work (e.g. contract research institutes), they must ensure that this research is conducted in accordance with applicable legal and ethical provisions, including the valid provisions of this Code of Conduct.

2. Product evaluation by the member company after launching the product

Insofar as a business need exists, member companies can commission third companies to evaluate their products, therapies, and/or associated services after launching them on the market and, in the course thereof, provide evaluation products (see [Glossary](#)) to receive a detailed benefit assessment of the evaluation products from healthcare institutions. The

evaluation products may be made available at no cost in exchange for the requested user feedback from medical professionals at healthcare institutions. Provision of such products should always be formally recorded in writing in a protocol or survey as part of the contract.

If the evaluation products are reusable, the time period for which the product must be provided for free depends on the frequency of the intended use as well as the type of feedback requested in accordance with the user assessment and the duration of a necessary briefing. Member companies should always ensure that they remain the owner of reusable evaluation products and that an agreement is in place to return the products and/or unused single-use evaluation products after concluding the evaluation. This does not apply if the healthcare institution has purchased the products.

Medical professionals and/or healthcare institutions should not receive inappropriate payment for the provision of evaluation products and/or associated services. In addition, they should not be inappropriately prompted and/or encouraged to purchase, rent, recommend, prescribe, use, deliver, or acquire the products or services of the member company. Every offer and/or delivery of these evaluation products should always take place in accordance with the applicable laws, guidelines, and professional codes.

3. Research studies commissioned by third parties

See [Chapter 4: Grants and donations for charitable or other philanthropic purposes](#): *Research grants*.

Chapter 7: Licence fees

Medical professionals often make a valuable contribution to the improvement of products or medical technologies, alone or as part of a group in which they work as an active participant. They can also develop intellectual property, for example, patents, trade secrets, or know-how, as part of a development or licence agreement.

Member companies should only enter into a licence agreement with medical professionals if the medical professional is expected to make or has made a new, significant, or innovative contribution. This can apply to the development of a product, a technology, a procedure, or a method, for example, whereby the medical professional is considered the sole owner or co-owner of this intellectual property according to applicable laws. This applies irrespective of the member company's obligations to fulfil applicable obligations to pay licence fees that could arise in some countries according to valid laws.

The agreements to pay licence fees to a medical professional through or on behalf of the member company should always be regulated contractually in writing and constitute an appropriate amount according to applicable laws. For example, licence fees paid for intellectual property may not be tied to the condition

- that the medical professional purchase, order, or recommend the member company's products, services, or medical technologies or products or technologies developed as the result of a development project; or
- that this represents a requirement for marketing the products or medical technology after putting it into circulation.

Subject to national regulations and requirements, member companies should not take the units purchased, prescribed, used, or ordered by the medical professional and/or healthcare institution that employs them into account for calculating the licence fees. This must be regulated in the contract.

Chapter 8: Material for professional further training and gifts

In exceptional cases, member companies can provide material for professional further training and/or gifts, insofar as this occurs in accordance with nationally valid laws, guidelines, and professional codes. Member companies may only offer material for professional further training and/or gifts in compliance with the following basic principles and under consideration of the respectively applicable laws:

- a. Material for professional further training and/or gifts must be intended for use in the medical professional's medical practice and serve the purpose of the patients' well-being and/or further training.
- b. Material for professional further training and/or gifts are not provided upon request of a medical professional.
- c. Material for professional further training and/or gifts may not be given in the form of money or a cash equivalent (vouchers, etc.).
- d. Material for professional further training and/or gifts must be of nominal value and may or may not bear the company logo of the member company.
- e. Member companies can occasionally offer a healthcare institution material for professional further training at a higher value, as long as these materials actually serve the purpose of training the medical professionals in this healthcare institution and/or the serve the well-being of patients. Such materials may not be given to medical professionals for personal use. The material must also correspond with the therapy areas in which the member company operates. Member companies must document the delivery of material for professional further training of a higher value to healthcare institutions appropriately. Materials for professional further training should not be integrated into the usual administration and routine costs. The respectively valid legal limits must be taken into account.
- f. Delivering material for professional further training and/or gifts to medical professionals or healthcare institutions may not constitute an inappropriate incentive to purchase, rent, recommend, prescribe, use, deliver, or acquire the products or services of the member company.

Prize draws and other forms of competition are only permitted at events if the intended prize meets the requirements set out in *Chapter 8: Material for professional further development and gifts*. In addition, such competitions must comply with national laws, guidelines, and professional codes.

This chapter is not intended to restrict the common practice of offering evaluation products, demonstration products, or samples in a reasonable measure. Further stipulations on offering evaluation products, demonstration products, or samples are detailed in [Chapter 6: Research](#) and [Chapter 9: Demonstration products and samples](#).

Chapter 9: Demonstration products and samples

1. General principles

Member companies can provide their own products free of charge as demonstration products and/or samples (see [Glossary](#)) in order to enable medical professionals and/or, where appropriate, healthcare institutions to evaluate and/or familiarise themselves with the safe, effective, and appropriate use and functionality of the product and/or associated service as well as to determine if or when the product and/or the service should be used, ordered, purchased, prescribed, or recommended in the future.

Demonstration products and samples can be either single-use or reusable products. Member companies can, as an exception, also provide another company's products insofar as this is necessary to correctly and effectively present, evaluate, or use the member company's products, e.g., computer hardware and software that was not manufactured by the member company.

Medical professionals and/or healthcare institutions should not receive unreasonable benefits through the provision of demonstration products and/or samples. Furthermore, they should not be inappropriately prompted and/or encouraged to purchase, rent, recommend, prescribe, use, deliver, or acquire the products or services of the member company. Every offer and/or delivery of such products must take place in accordance with national laws, guidelines, and professional codes.

Member companies should always appropriately document the provision of demonstration products and/or samples to medical professionals and/or healthcare institutions, e.g. the delivery and, in case of reusable products, their return. In addition, member companies should clearly document, and clearly notify the medical professionals and/or medical institutions that these demonstration products and/or samples are provided free of charge. This information must be communicated in writing before delivery of the product and also contain all stipulations associated with the provision of this product.

This chapter is restricted to the free provision of demonstration products and/or samples and associated services and does not apply to the provision of products or associated services set out in other agreements, including (but not limited to) provision within the framework of clinical studies and/or other research work or for commercial purposes in the form of discounts or price reductions within the framework of public procurement processes.

2. Demonstration products

Member companies can provide both medical professionals and healthcare institutions with demonstration products (see [Glossary](#)) in the form of teaching models (e.g., non-sterilised, single-use products) that serve the purpose of informing, educating, and training medical professionals and patients. The respective legal requirements must be reviewed.

For example, a medical professional can use a demonstration product to explain to a patient a type of technology that will be implanted in this patient, or the medical professional can use a demonstration product to train other medical professionals in using the product.

Demonstration products are not intended for clinical use on patients, nor should they be sold or passed on in any other way.

Member companies should ensure appropriate documentation of the provision of demonstration products and inform the medical professionals or the healthcare institution that these demonstration products and/or samples are provided free of charge. This information must be communicated in writing before delivery of the product and must also contain all stipulations tied to its provision.

3. Samples

Member companies can provide a reasonable number of samples (see [Glossary](#)) free of charge in order for medical professionals or healthcare institutions to familiarise themselves with the products and/or associated services. This enables them to gain experience in the safe and effective use of the product or service in a clinical application in order to determine if and when the products and/or services should be used, ordered, purchased, prescribed, or recommended in the future.⁵

Only as many single-use samples for testing as necessary for gaining sufficient experience in using the products should be made available.

For reusable samples, the set testing time depends on the frequency of intended use, the duration of the training itself, the number of medical professionals that are to gain experience in using the product, and other, similar, considerations. In any case, member companies must make sure that they remain the owners of reusable samples and that it has been agreed that these will be returned immediately after concluding the demonstration phase.

⁵ Depending on the product, the test phase should be limited to what is necessary with respect to the number of products and duration. This primarily depends on the type of product, the complexity of use, and the frequency of use in a practice or in a medical institution.

PART 2: Disclosure guidelines

Foreword

Under the SPECTARIS Code of Conduct, as of 1 January 2020, member companies should avoid paying registration fees, travel, or hospitality costs directly to the medical professional when they participate in further education conferences organised by third parties.

In accordance with the rules set out by the code, support for medical further training can be offered through educational grants provided to healthcare institutions. To prevent misuse, special (security) measures have been developed, including the voluntary obligation to disclose these educational grants.

Section 3 of Chapter 4 states that member companies should document and make public all educational grants in accordance with these disclosure guidelines. Accordingly, these disclosure guidelines form a crucial component of the code and should be interpreted correspondingly.

To avoid doubts, all grants to promote actual educational purposes provided by member companies to a professional conference organiser (“PCO”) acting independently of healthcare institutions fall under the scope of these disclosure guidelines and are subject to the same conditions as educational grants. Insofar as these educational grants apply to healthcare institutions, professional conference organisers are also included.

Chapter 1: Applicability of these guidelines

1. Scope

These disclosure guidelines apply to member companies and their interactions with healthcare institutions based or registered in Germany and Europe.

Separate units that are part of the same multinational company (“branches”) – these may include parent companies (e.g., headquarters, registered offices, or the umbrella company of a commercial corporation), a subsidiary company, or any other form of company or organisation – should be viewed as an individual company and as such should feel obligated to comply with these disclosure guidelines.

The transfer of values that are not included in the definition of further education scholarships (as described in Chapter 4, Section 3 of this code) and which consequently cannot be allocated to a category listed in *Section 2.2. Collective disclosure* are not subject to these disclosure guidelines.

2. Applicability of these disclosure guidelines

Member companies should not provide the same information twice if they are also obliged to do so due to national laws, regulations, or professional codes that require disclosure provisions regarding educational grants (see Chapter 4, Section 3 of this code) that correspond to these disclosure guidelines.

3. Applicability for non-member companies

Non-member companies can also use these disclosure guidelines, provided they are committed to ethical standards that match the recommendations of this code.

Chapter 2: Obligation to disclose

1. General obligation

In accordance with the provisions of these disclosure guidelines, every member company should document and disclose all payments related to educational scholarships (as described in Chapter 4, Section 3 of the code) that it provides to a healthcare institution based or registered in Europe, without limitation of the amount.

All branches of a member company that are registered in Germany and Europe should disclose the educational grants of branches of member companies, as described above, that are not registered in Germany or Europe.

2. Collective disclosure

Educational grants should be disclosed collectively. Every branch of a member company should disclose the amounts, separately for every clearly identifiable recipient, that this recipient has received in the form of educational grants that can reasonably be allocated to one of the categories listed below during the respective reporting period. These amounts are collected and depicted on a category-by-category basis. However, an individually listed disclosure must be made available, if required, upon request of the member company for the (i) relevant recipient or (ii) the relevant authority.⁶

Member companies should disclose a collective amount, allocated to one of the following categories:

⁶ The data protection laws of the respective country must be taken into account.

- a. Educational grants to support events organised by third parties (including funding of participation of medical professional in events organised by third parties) and
- b. Other educational stipends given to healthcare institutions (including scholarships, fellowships, or grants for awareness campaigns).

3. Optional object specification

If desired, member companies can allocate the purpose of a disclosed educational grant to one or both categories listed in *Section 2.2 Collective disclosure*.

4. Methodology

Every member company should draft a report that summarises the methodology used to create the disclosure and identification of educational grants for every category described in *Section 2.2 Collective disclosure*. The report, including a general summary or country-specific considerations, should describe the recognition methods and contain a depiction of how they dealt with VAT and other tax and currency aspects, as well as other matters concerning time and the amount of the educational grants.

Chapter 3: Type of disclosure

1. Reporting period

Disclosures are made on an annual basis, and each reporting period comprises an entire calendar year.

2. Time of disclosure

Disclosures are made by every member company within 6 months after the end of the respective reporting period.

3. Time of publication

The disclosure occurs at the time of publication. The time of publication is 31 August of the year of the respective disclosure period.

4. Presentation and language of the disclosure

For purposes of conformity, in accordance with these disclosure guidelines, disclosures are to be made in English using the template provided in the annex.

5. Disclosure platform

Disclosures should be made on the EthicalMedTech⁷ website, unless a member company is already obligated to disclosure through national laws, regulations, or professional codes (set out in *Section 1.2 Applicability of these guidelines*). Member companies remain liable for the correctness of the disclosed data. MedTech Europe is neither liable for (i) maintaining, correcting, or deleting the published data nor for (ii) storing the data after the 3-year period of disclosure in the public domain.⁸

6. Maintaining and adapting the disclosures

Member companies can modify, delete, or change their disclosures in any way before or after publication.

Disclosed information remains in the public domain for three years after this information is first published.

7. Inquiries regarding submitted disclosures

Member companies can modify, delete, or change their disclosures in any way before or after publication.

Member companies should provide health institutions with all data concerning their contractual relationship which were published in accordance with these guidelines, for the entire duration in which the disclosed information remains in the public domain, as indicated in *Section 3.3 Time of publication*.

PART 3: Glossary and definitions

- **Application training organised by third parties:** A type of further education event organised by third parties that primarily serves to provide information and training to medical professionals to ensure the safe and effective use of one or more clinical procedures. These include the following:

⁷ The database still has to be set up.

⁸ The respective data protection regulations must be taken into consideration.

- special therapeutic, diagnostic, or rehabilitative procedures, i.e. clinical application possibilities, methods, or techniques; and
- practical demonstrations and/or training for medical professionals, whereby the majority of the training programme takes place in a clinical environment.

Work shadowing and proctorships⁹ do not fall under this category of further education events.

- **Educational grants:** The provision of financial grants and/or products made by the member company or a third party, or other non-monetary benefits given to a healthcare institution by or on behalf of a member company, that are exclusively intended to support and promote the medical training, further education, and continuing development of medical professionals, patients, and/or the public on clinical, scientific, and/or health policy topics and belong to the therapy area in which the member company operates.
- **Training, further education, and continuing development events organised by third parties (external further education events):** All kinds of activities that are fully or partially planned, managed, and run by or on behalf of a person or unit other than the member company with the purpose of covering a medical training need for medical professionals.
- **Training, further education, and continuing development conferences organised by third parties (external further education conferences):**
A type of further education event organised by third parties that takes the form of an independent, educating, scientific, as well as opinion-forming conference set up to promote scientific knowledge, medical advances, and/or the provision of effective healthcare, and that fulfils the respective guidelines set out by professional associations or organisations. Such events usually constitute conferences organised by national, regional, or special medical associations and/or societies, hospitals, professional conference organisers, patient organisations, or event organisers accredited for medical training.
- **Notifying the employer:** This refers to sending an advance written notification to a healthcare institution (e.g., the hospital administration), the superior of a medical professional, or another responsible authority on site regarding the purpose and scope of all interactions, collaborations, or other matters between a member company and a medical professional that require such notification according to the Code of Conduct at hand.
- **Conference Vetting System:** A central decision-making procedure that monitors compliance with the code at training, further education, and continuing development events organised by third parties and is conducted under the supervision of the MedTech Europe Compliance Panel, but independently of MedTech Europe. Further information can be found at <http://www.ethicalmedtech.eu>.
- **Demonstration products:** Free single-use and/or reusable products that are given to healthcare institutions or medical professionals who have the necessary technical equipment and professional competence to use such demonstration products provided by or on behalf of a member company. The demonstration products are made available exclusively for the

⁹ See Q&A 21 in the English version of the MTE code for the definition of “proctorship”.

purpose of demonstrating the safe and effective use and appropriate functionality of a product. They are not intended for clinical use. Demonstration products do not include the following:

- samples;
 - evaluation products;
 - products that are made available for free as part of a donation for charitable purposes or as part of a research grant or an educational stipend; or
 - products that are provided at no extra cost as part of an entire purchasing volume within the framework of a business agreement, e.g. as part of a discount agreement or replacement products that are delivered in accordance with a guarantee agreement.
- **Healthcare institution:** A legal unit or a legal entity (regardless of the legal or organisational form) that is a health policy, medical, or scientific association or organisation, has direct or indirect influence on the prescription, recommendation, purchase, order, delivery, use, distribution, or rental of medical technologies or associated services, e.g. hospitals or purchasing groups, clinics, laboratories, pharmacies, research institutes, foundations, universities or other educational institutions, as well as professional associations or scientific societies (with the exception of patient organisations); or institutions through which one or more medical professionals provide services.
 - **Evaluation products:** Either single-use or reusable products and/or other equipment that a member company makes available, or that are made available on their behalf, to a healthcare institution free of charge with the aim of receiving feedback from users who have employed the products in accordance with the intended use and within the framework of national regulations and for a defined application duration. Evaluation products do not include the following:
 - demonstration products;
 - samples;
 - products that are made available free of charge as part of a donation for charitable or other philanthropic purposes or as part of a grant for scientific purposes or for further education purposes; or
 - products that are provided at no extra cost as part of an entire purchasing volume within the framework of a business agreement, e.g., as part of a discount agreement or replacement products that are delivered in accordance with a guarantee agreement.
 - **Research grant:** The provision of financial grants, products, and/or other technical equipment and/or other non-monetary benefits to research institutions by or on behalf of a member company. These must exclusively serve the purpose of supporting the development or promotion of scientifically valid and serious research work that aims to advance knowledge on medical, scientific, and health policy topics, medical technologies, and/or clinical techniques to improve patients' well-being.
 - **Guests:** Spouses, partners, family members, or guests of medical professionals as well as other individuals who have no professional interest in the information presented at the event.

- **Internal company events:** All types of activities that are fully or partially planned, managed, and run by or on behalf of a member company to fulfil a legitimate, documented business need of a member company, including but not limited to the legitimate business need to work together with customers, which also includes medical professionals and/or healthcare institutions.
- **Code:** This refers to the existing SPECTARIS Code of Conduct on ethical business conduct, including the disclosure guidelines.
- **Medical professional:** Persons (with a clinical or non-clinical occupational background; government officials or employees as well as representatives of a government authority or another public or private institution; including but not limited to doctors, nurses, technicians, laboratory scientists, researchers, research directors, or buyers) who, over the course of their professional activities, directly or indirectly purchase, rent, recommend, administer, deliver, or procure medical technologies or associated services, and who make decisions about purchasing or renting these, or prescribe medical technologies.
- **Members:** All full and associate member companies of the SPECTARIS professional association for medical technology.
- **Sample:** Single-use or reusable products made available by or on behalf of a member company free of charge to medical professionals or healthcare institutions. Medical professionals or healthcare institutions must demonstrate the necessary technical equipment and professional competence to use such products and be able to familiarise themselves with them in the clinical area. Samples do not include the following:
 - demonstration products;
 - evaluation products;
 - products that are made available for free as part of a donation for charitable purposes or as part of a research grant or an educational stipend; or
 - products that are provided at no extra cost as part of an entire purchasing volume within the framework of a business agreement, e.g., as part of a discount agreement or replacement products delivered in accordance with a guarantee agreement.
- **Product and application training and further education events:** An internal company event primarily intended to serve the further education of medical professionals. This includes information and/or training on:
 - the safe and effective application of medical technologies, therapies, and/or associated services, and/or
 - the safe and effective performance of clinical procedures and/or on associated disease areas.
 - Member companies can only offer information and/or training on medical technologies and relevant therapies and/or associated services in the area in which the member company operates.
- **Professional conference organiser:** Profit-orientated companies or organisations specialised in organising congresses, conferences, seminars, and similar events.

- **Speaker:** An orator, moderator, and/or chair who gives a lecture or presentation at a training, further education, or continuing development event organised by a third party. Medical professionals presenting posters on the occasion of a congress are not referred to as speakers.
- **Disclosure guidelines:** Provisions which regulate the disclosure obligations of member companies.
- **Donations for charitable purposes:** The provision of cash, equipment, company products, or relevant products from third parties, exclusively to be used for charitable or philanthropic purposes. Donations for charitable purposes can only be made without a specified use and benefitting charitable organisations or other non-profit institutions whose main objective lies in fulfilling a non-profit purpose.
- **Scholarships and fellowship programmes:** Educational grants provided to a healthcare institution by or on behalf of the member company to support fellowship or scholarship programmes offered by the healthcare institution. In this context, scholarship refers to an educational grant to support a medical student, while a fellowship programme designates an intensive postgraduate educational time period for doctors who have completed their studies in a specific clinical field (e.g., further medical training following specialist medical training).
- **Entertainment:** Entertainment includes, but is not limited to, dance events or events at which live music forms the main attraction, sightseeing excursions, theatre visits, sports activities (e.g., skiing, golf, or football games), as well as other leisure activities. Accompanying background music does not qualify as entertainment.
- **Transition phase:** The time from 1 January 2016 to 31 December 2017, after which the member companies may no longer give direct financial or material support to medical professionals to cover their costs for participating in training, further education, and continuing development events organised by third parties. Exceptions include application training organised by third parties or the service of a medical professional who was hired by a member company within the framework of a consulting contract to speak at a satellite symposium.
- **Event:** Either an internal company event or a training, further education, or continuing development event organised by third parties.
- **Sales, marketing, and other business meetings:** Any internal company event with the goal of selling or promoting medical technologies and/or associated services of a member company, including meetings for discussing product features, advantages, and applications and/or delivery conditions.
- **Grants:** Either an educational grant or research grant, or both.

Berlin, September 2017