

A close-up, low-angle shot of a microscope's objective lens and stage, with a hand visible in the background. The image is overlaid with a dark blue and purple gradient.

# **IMEDA Code of Ethical Business Practice**

## **December 2019**

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# Contents

INTRODUCTION .....	4
Promoting an Ethical Industry .....	4
Key Legislation .....	4
Aims and Principles of the Code .....	5
Interpreting the Code .....	6
Administering the Code .....	6
Implementation and Transition Period .....	7
PART 1: Guidelines on the Interactions with Healthcare Professionals and Healthcare Organisations .....	8
Chapter 1: General Criteria for Events .....	9
Chapter 2: Third Party Organised Educational Events .....	13
1. Third Party Organised Educational Conferences .....	<b>Ошибка! Закладка не определена.</b>
2. Third Party Organised Procedure Training .....	<b>Ошибка! Закладка не определена.</b>
Chapter 3: Company Events .....	16
1. General Principles .....	16
2. Product and Procedure Training and Education Events .....	16
3. Information Meetings .....	17
Chapter 4: Grants and Charitable Donations .....	19
1. General Principles .....	19
2. Charitable Donations .....	20
3. Educational Grants .....	21
4. Research Grants .....	24
Chapter 5: Service Arrangements .....	26
1. General Principles .....	26
2. Criteria for service arrangements .....	26
3. Remuneration and Fair Market Value .....	27
4. Disclosure and Transparency .....	27
Chapter 6: Research .....	29
1. Company-Initiated Research .....	29
2. Company Post-Market Product Evaluation .....	29
3. Third Party-Initiated Research .....	30
Chapter 7: Royalties .....	31
Chapter 8: Educational Items and Gifts .....	32
Chapter 9: Demonstration Products and Samples .....	33
1. General Principles .....	33
2. Demonstration Products (Demos) .....	34
3. Samples .....	34
PART 2: Disclosure Guidelines .....	35
Preamble .....	36
Chapter 1: Applicability of these Guidelines .....	37
1. Scope .....	37
2. Applicability of these Disclosure Guidelines .....	37
Chapter 2: Disclosure Obligation .....	38
1. General Obligation .....	38
2. Aggregate Disclosure .....	38
3. Optional Object Specification .....	38
4. Methodology .....	39

Chapter 3: Form of Disclosure .....	40
1. Reporting Period .....	40
2. Time of Disclosure .....	40
3. Time of Publication .....	40
4. Template and Language of Disclosure .....	40
5. Platform of Disclosure .....	40
6. Retention and Modification of the Disclosures .....	40
7. Enquiries Regarding Reported Disclosures .....	41
PART 3: Glossary .....	42
Annexes .....	42

# INTRODUCTION

## Promoting an Ethical Industry

IMEDA is the Russian trade association representing the medical technology industry from diagnosis to cure. We represent In-Vitro Diagnostics and Medical Devices manufacturers operating in Russia. Our mission is to promote a balanced environment that enables the medical technology industry to meet the growing healthcare needs and expectations of its stakeholders.

IMEDA recognises that compliance with applicable laws and regulations as well as adherence to ethical standards are both an obligation and a critical step to the achievement of the aforementioned goals and can enhance the reputation and position of the medical technology industry.

The Code sets out the minimum standards appropriate to the various types of activities carried out by the companies-members of IMEDA (hereinafter - "Companies"). The Code is not intended to supplant or supersede laws or regulations applicable on the territory of the Russian Federation that may impose more stringent requirements upon Companies and all Companies should independently ascertain that their activities comply with all laws and regulations applicable on the territory of the Russian Federation. Furthermore, Companies must be mindful of the fact that they may be liable for the activities of third party intermediaries who interact with Healthcare Professionals or Healthcare Organisations in connection with the sale, promotion or other activity involving Companies' products. Accordingly, it is recommended that where such arrangements are entered into, the relevant contractual documentation impose obligations upon the third party (for example, third party sales & marketing intermediaries (SMIs), consultants, distributors, sales agents, marketing agents, brokers, commissionaire commercial agents and independent sales representatives) to comply with provisions set out in the Code or equivalent guidelines of the Companies.

## Key Legislation

The medical technology industry in Russia, in common with other industries, is subject to national and supranational laws which govern many aspects of their business operations. IMEDA underlines compliance with the following laws and regulations as having particular relevance to the medical technology industry:

- Laws on fundamentals of citizens' health, including on safety, quality and performance requirements ;
- Advertising Laws;
- Personal Data Protection Laws;
- Anti-corruption Laws;
- Environmental Health and Safety Laws;
- Competition Laws.

National and EurAsian Economic Union (EAEU) competition legislation applies not only to Companies in their business operations, but also to IMEDA, committees, each of its working groups and any sub-group, irrespective of size and name. Liability under competition laws may be strict and a

Company may become liable for the infringement of such laws by other Companies of an association group. Accordingly, Companies must make every effort to observe EAEU regulations and national competition laws in all their interactions.

## Aims and Principles of the Code

The interaction between Companies and Healthcare Professionals and Healthcare Organisations is an important feature in achieving IMEDA's mission to make safe, innovative and reliable technology and related services available to more people. For example:

- **Advancement of Medical Technologies**  
The development of innovative medical devices, technologies and in vitro diagnostics and the improvement of existing products require collaboration between Companies and Healthcare Professionals and Healthcare Organisations. Innovation and creativity are essential to the development and evolution of medical technologies and/or related services.
- **Safe and Effective Use of Medical Technology**  
The safe and effective use of medical technology and related services requires Companies to offer Healthcare Professionals and Healthcare Organisations appropriate instruction, education, training, service and technical support.
- **Research and Education**  
Companies' support of genuine medical research and education, serves to enhance Healthcare Professionals' clinical skills and thereby contribute to patient safety and increase access to new technologies and/or related services.

In each such interaction Companies must continue to respect the obligation of Healthcare Professionals to make independent decisions regarding treatment and safeguard the environment in which the interaction takes place to ensure the integrity of the industry. To achieve this aim, the Code provides guidance on the interactions of Companies with both Healthcare Professionals and Healthcare Organisations, based upon the following underlying principles:

- **The Principle of Image and Perception:** When interacting with Healthcare Professionals and Healthcare Organisations Companies should, at all times, consider the image and perception of the medical technology industry by the society.
- **The Principle of Separation:** Interaction between industry and Healthcare Professionals/ Healthcare Organisations must not be misused to influence through undue or improper advantages, purchasing decisions. Such interaction should also not be contingent upon sales agreements or use or recommendation of Companies' products.
- **The Principle of Transparency:** Interaction between industry and Healthcare Professionals Healthcare Organisations must be transparent and

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

*A1: No, the definition of Healthcare Professional does not include a purchasing professional employed in the retail sector unless that individual purchaser arranges for the purchase of Companies' medical devices for or on behalf of medical or clinical personnel. For example, if a Company's medical devices are sold as part of the common merchandise of the retail outlet, interactions between the Company and the purchasing professional do not fall under the Code. However, where the Company's medical devices are sold in a retail pharmacy (even if this is located within a supermarket unit), interactions between the Company and the responsible purchasing professional will fall under the Code.*

*Q2: Must a Company require Employer Notification to be given whenever Company personnel meet HCPs at an HCO?*

*A2: No. Unless the Company's interaction with an HCP entails a transfer of value or raises a potential conflict of interest there is*

comply with laws and regulations applicable on the territory of the Russian Federation. Companies shall maintain appropriate transparency by requiring prior written notification to the hospital administration or the Healthcare Professional's superior, fully disclosing the purpose and subject of the interaction.

- **The Principle of Equivalence:** Where Healthcare Professionals are engaged by a Company to perform a service for or on behalf of a Company within the limits of the current legislation, the remuneration paid by the Company must be commensurate with, and represent a fair market value for, the services performed by the Healthcare Professional.
- **The Principle of Documentation:** For interactions between a Company and a Healthcare Professional, such as where services are performed by a Healthcare Professional for or on behalf of a Company, there must be a written agreement setting out, inter alia, the purpose of the interaction, the services to be performed, the method for reimbursement of expenses as well as the remuneration to be paid by the Company. The activities envisaged by the agreement must be substantiated and evidenced by activity reports and the like. Adequate documentation such as the agreement, related reports, invoices etc. must be retained by the Company for a reasonable period of time to support the need for, and materiality of, the services as well as the reasonableness of the remuneration paid.

*no requirement for Employer Notification. However, Companies must comply with any access requirements imposed by HCOs to visiting Company personnel.*

## Interpreting the Code

The use of capital letters indicates that a word or expression is a defined term, the meaning of which is set out in the [Glossary](#).

Any phrase introduced by the terms: including, include, in particular, or any similar expression shall be interpreted as illustrative and shall not limit the sense of the words preceding those terms.

## Administering the Code

The [Conference Vetting System](#) is an independently-managed system which reviews the compliance of Third Party Organised Educational Events with the Code.

The Code is subject to revision as may be required from time to time.

*Q3: What is the Conference Vetting System (CVS) and, is CVS approval required for all Third Party Organised Educational Events before a Company can provide support to these events?*

*A3: The Conference Vetting System (see the Glossary) has been established as the online, binding and centralised decision-making process to help Companies review the compliance of relevant Third Party Organised Educational Events with the Code. It is managed independently of IMEDA and Companies and is under the supervision of the MedTech Europe Compliance Panel. CVS approval is only required for Third Party Organised Educational Events which fall within its scope, as provided [here](#). Where there is a CVS decision in relation to a specific Third Party Organised Educational Event, this decision is binding upon all Companies.*

# Implementation and Transition Period

This Code comes into force on 1 January 2020.

However, starting from 1 January 2020 until 31 December 2020 there is a transition period during which at the Company's discretion it can comply with the provisions of the Code immediately starting from 1 January 2020, or postpone the application of the Code until 1 January 2021 and comply during the transition period with the provisions of the Code of Ethical Conduct for Interactions with Healthcare Professionals of the International Medical Device Manufacturers Association 2013 with simultaneous preparations for application of this Code starting from 1 January 2021.

For avoidance of doubt, materials and actions of Companies which do not comply with this Code, but which comply with the Code of Ethical Conduct for Interactions with Healthcare Professionals of the International Medical Device Manufacturers Association 2013, will not be considered as violation of the Code.

However, all Companies must be guided by the Code in its activities.

The Dispute Resolution Principles shall be developed within the scope of the Code until 31 December 2020 and implemented starting from 2021.

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

*A4: Implementation means the process of incorporating the Code within the Company's own policy and procedures. This process must be completed by 1 January 2021.*

*Transition Period means the period between 1 January 2020 and 31 December 2020 by the end of which Companies must comply with the Code to full extent.*

*Q4-bis: How does the Code apply to Companies with company structures that include different business units e.g., medical devices, pharmaceuticals, research only products? How can educational grants be applied in such organizational structures?*

*A4-bis: The Code applies to all Companies regarding their interactions linked to Medical Technologies. Ensuring compliance with the Code may be more challenging for companies with structures combining different business units, however Companies are required to comply with the Code as a minimum standard for all interactions linked to Medical Technologies independent of their organizational set up. For example, if a Company were to have Medical Devices or In Vitro Diagnostics marketed under or linked to their pharmaceutical business unit, the interactions with Healthcare Professionals and Healthcare Organisations in relation to these medical technologies would be governed by the Code irrespective of the business unit that pays for or manages the interaction. In this respect, the Company cannot circumvent the Code's requirements by using its pharmaceutical business/affiliate to directly support a Healthcare Professional to attend a medical technology related Third Party Organised Educational Conference as this would amount to a violation of the Code. For the avoidance of doubt, the Code will not apply to Companies' interactions linked exclusively to non-Medical Technology products or services such as medicinal products or research only products, without any link to Medical Technology products. However, this does not mean that different business units can be used to circumvent Code requirements as explained above. In case an interaction or activity is linked in part to Medical Technology products, the Code shall apply.*



# PART 1: Guidelines on the Interactions with Healthcare Professionals and Healthcare Organisations



# Chapter 1: General Criteria for Events

The principles and criteria set out in this Chapter 1 shall apply to all Company Events and Third Party Organised Educational Events supported in any way by Companies, irrespective of who is the Event organizer.

## 1. Event Programme

The Event programme should directly relate to the specialty and/or medical practice of the Healthcare Professionals who will attend the Event or be sufficiently relevant to justify the attendance of the Healthcare Professionals. For Third Party Organised Educational Events, the agenda should be under the sole control and responsibility of the third party organiser.

A Company shall not organise Events which include social, sporting and/or leisure activities or other forms of Entertainment, nor support such elements where part of Third Party Organised Educational Events. For Third Party Organised Educational Events, Entertainment must be outside of the educational programme schedule and paid for separately by the Healthcare Professionals. Entertainment should not dominate or interfere with the overall scientific content of the programme and must be held during times that do not overlap with a scientific session. The Entertainment should not be the main attraction of the Third Party Organised Educational Event.

## 2. Event Location and Venue

The Event location and venue should not become the main attraction of the Event. For the location and the venue, Companies must take into account at all times the following considerations:

- Potential adverse public perceptions of the location and venue for the Event. The location and venue must not be perceived as luxury, or tourist/holiday-oriented, or that of an Entertainment venue.
- The Event location and venue should be, to the extent possible, equidistant from the places of residence of the majority of invited participants.
- The need for ease of access for attendees.
- The Event location and venue should be in or near a city or town which is a recognised scientific or business centre, suitable for hosting an Event which is conducive to the exchange of ideas and the transmission of knowledge.
- Companies must take into account the season during which the Event is held. The selected time of year must not be associated with a touristic

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

*A5: Any Event should be relevant to the Healthcare Professional attendees; the detailed programme should be available sufficient time prior to the Event; present a clear schedule with no gaps during the sessions, (e.g., the minimum duration for a full day Event should be 6 hours or 3 hours for a half day Event including refreshment breaks). If it is a Third Party Organised Educational Event, the Faculty must be identified. It is also important that all supporting materials (e.g. flyers, brochures and website) are consistent with the scientific or promotional nature of the programme content, as the case may be.*

*Q6: Can a Company organise or support an Event at a hotel or resort that offers significant leisure facilities such as golf, casino or ski/ water sports?*

*A6: As a general rule no. It is not appropriate for a Company to organise or support Events at hotels or resorts renowned for their entertainment facilities or centred around recreational or sporting activities such as golf, private beach or ski/water sports.*

*Exceptions might be considered for venues well adapted to business meetings in geographic locations compliant with the Code where there is a compelling need to use the chosen venue, for example, a lack of alternative venues or genuine safety or security issues. In certain circumstances, hotel accommodation separate from the Third-Party Organised Event venue might be required for compliance.*

*Where an exception is considered, the Event's promotional material should not feature the onsite leisure aspects of the conference venue as a key attraction of the Event, and the Event's agenda should be arranged in such a way that attending Healthcare Professionals would not be free to make use of the leisure and sporting facilities during a significant part of a normal working day. Further, where hotels require additional payment to use the leisure or sporting facilities, Companies may not make such payments on behalf of the*

season for the selected geographic location.

*Healthcare Professionals.*

*For reasons of perception, cruise ships or hotels with on-site casinos are under no circumstances compliant with the Code, either as an Event venue or for accommodation for Healthcare Professionals.*

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

*A7: When originating location of the majority of attendees is considered, Event location and venue need to be in close proximity to an airport and / or train station with appropriate international connections, with associated reliable ground transportation infrastructure to the venue.*

*Q8: Under the Code, how does the "season" impact evaluation of Event location?*

*A8: Even assuming a location or venue meets all other applicable requirements under the Code, geographic locations renowned primarily as seasonal vacation or holiday destinations (for example, ski-, island-, or beach resorts) are still not permissible locations during the season in question. For this purpose, in Europe, including Russia, the ski season is considered to run from December 20 - March 31 and the summer season from June 1 - September 15. Equivalent, seasonally and climatically adjusted dates apply in other regions of the world. Companies must not support or organise Events at these locations if they take place during those seasons, even in case of partial overlap.*

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

*A9: The term "facilitate" refers to the prior approval, organisation or booking of meals, travel or accommodation by or on behalf of a Company on behalf of the Guest of a Healthcare Professional participant. Such organisation or booking is not permitted unless the individual qualifies as a participant in his/her own right, irrespective of who pays. Such actions are open to misinterpretation. If Healthcare Professionals attending the Event wish to be accompanied by a Guest who does not have a professional interest in the information being shared, the Healthcare Professional must take sole responsibility for the payment and organisation of the Guest's expenses.*

*Q10: In the event that a Healthcare Professional is accompanied by a Guest at the Event, may this Guest be admitted to any Company Event, or Third Party Organised Educational Events?*

*A10: It is not appropriate for a Guest of a Healthcare Professional to attend either Company Events (including Satellite Symposia) or Third Party Organised Educational Events (unless the individual qualifies as a participant in their own right), nor is it appropriate, in the interest of maintaining the scientific exchange, for a Guest to participate in related hospitality during such Events (for example, lunches and coffee breaks) even when the Healthcare Professional pays for the Guest's expenses. Companies, however, may financially support Third Party Organised Educational Events which offer extra-curricular programmes/ activities beyond the scientific, educational or training sessions for Guests of Healthcare Professionals (such as touristic activities and hospitality), always provided that such an extra-curricular programme/activity (including attendance of the conference dinner or a cocktail reception) is subject to a separate charge which must not be paid for, facilitated or reimbursed by, a Company.*

### 3. Guests

Companies are not permitted to facilitate the organization or pay for meals, travel, accommodation or other expenses for Guests of Healthcare Professionals, or for any other person who does not have a professional interest in the information being shared at the Event.

#### 4. Reasonable Hospitality

Companies may provide reasonable hospitality to Healthcare Professionals in the context of Company Events and, if appropriate, Third Party Organised Educational Events (e.g. within the framework of satellite congress organized by the Company) but any hospitality offered must be subordinate in time and focus to the main Event purpose. Companies must in any event meet the requirements governing hospitality in the country where the Healthcare Professional carries on their profession and give due consideration to the requirements in the country where the Event is being hosted.

The Code seeks to find a balance between the hospitality and professional treatment of Healthcare Professionals by Companies, with the desire to avoid even the appearance that hospitality elements may be used by Companies as a means to induce Healthcare Professionals to purchase, prescribe or recommend Companies' products.

Accordingly, Companies must assess what is "reasonable" in any given situation, taking into account regional variations. As a general rule, "reasonable" should be interpreted as the appropriate standard for the given location and must comply with laws, regulations and professional ethics codes, applicable on a specific territory. The term "hospitality" includes buffet style meals or meals and accommodation, if provided to the Healthcare Professionals engaged by Companies under the permitted service arrangements. It is important that Companies understand the difference between "hospitality" which is permitted and Entertainment which is not. Please refer to the [Glossary](#) for the definition of Entertainment.

Companies may not pay for or reimburse lodging expenses of Healthcare Professionals engaged by Companies under the permitted service arrangements at luxury hotels of top category. If the Event venue is a hotel which complies with the requirements of the Code, it would be acceptable for Companies to offer Healthcare Professionals engaged by Companies under the permitted service arrangements meals and accommodation at the same hotel. However, accommodation provided to Healthcare Professionals engaged by Companies under the permitted service arrangements should not cover a period of stay beyond the official duration of the Event, with a possibility to arrive one day before the Event and one day after the Event in case there is a logistics necessity.

#### 5. Travel costs

Companies may only pay or reimburse for actual and reasonable in terms of cost and itinerary travel of Healthcare Professionals engaged by Companies under the permitted service arrangements. Travel provided to Healthcare Professionals should not cover a period of stay beyond the official duration of the Event, with a possibility to arrive one day before the Event and one day after the Event in case there is a logistics necessity.

For air travel, in principle, this means that Companies can only pay or reimburse economy or standard class unless the flight time is of a duration of greater than 5 hours including connection flights, in which case business class can be considered. First class is never appropriate.

*Q11: May Companies offer to cover the travel and accommodation expenses of Healthcare Professionals for periods that extend beyond the duration of the Event programme attended?*

*A11: Generally, travel and accommodation support offered by Companies to Healthcare Professionals should be tailored to the duration of the Event and to the permitted service arrangement with Healthcare Professionals. Companies may cover the travel and accommodation expenses of Healthcare Professionals for one day before the Event and/or one day after the Event in case there is a logistics necessity. Companies must always keep in mind the impression, which may be created by the arrangements for any meeting.*



# Chapter 2: Third Party Organised Educational Events

Companies may provide financial and/or in kind support (e.g. Company products) to Third Party Organised Educational Events in accordance with the rules of this Code. Such Events include:

- Third Party Organised Educational Conferences; and
- Third Party Organised Procedure Training meetings.

## 1. Third Party Organised Educational Conferences

Companies may support in cash and/or in kind Third Party Organised Educational Conferences (see the Glossary) which:

- comply with Chapter 1: General Criteria for Events; and
- where applicable, have positive evaluation in the Conference Vetting System (see the Glossary)<sup>1</sup>.

Companies may provide financial and/or in kind support to Third Party Organised Educational Conferences (always provided that it has been positively assessed via the Conference Vetting System, where appropriate) in accordance with laws and regulations applicable on the territory of Russian Federation through grants and other types of funding, such as:

### a. Educational Grants

Please refer to Chapter 4: Charitable Donations and Grants for additional information on Grants.

### b. Promotional Activity

Companies may purchase sponsor packages that may include promotional and advertising services, for example, advertisement space and booth space for the display. Companies should ensure that the overall image projected by the promotional activity at Third Party Organised Educational Conferences is perceived as professional at all times. It should never bring discredit upon or reduce confidence in the medical technology industry.

*Q12: What is meant by “in kind support” as used in Chapter 2, Section 1 of the Code in connection with “Third Party Organised Educational Conferences”?*

*A12: “In kind support” can be provided to the Healthcare Organisation (HCO). However, Companies should take care to ensure that any such in kind support does not, nor is perceived to, circumvent the prohibition of Companies providing direct financial support to Healthcare Professionals (HCPs), whose identity may be established, to attend Third Party Organised Educational Conferences. For example, it would not be appropriate for Companies to directly handle the conference registration, travel, or accommodation arrangements for specific HCP delegates, whose identity may be established, at a Third Party Organised Educational Conference. Examples of “in kind support” which Companies may provide could include modest administrative and/or logistical support to assist with meeting arrangements.*

*Q13: Please provide examples of appropriate exhibition booth activities which will be perceived as professional?*

*A13: Exhibition booth activities at Third Party Organised Educational Conferences should aim primarily at displaying Companies’ products and services and related literature, as well as informing Event guests on Company’s products and services. Engagement of Healthcare Professionals for exhibition booth presentation is possible only if such presentation complies with criteria for satellite symposia set out in Annex VI hereto. Therefore, other booth activities should be limited and reasonable. It is permissible to serve at booths soft drinks and snacks only.*

*Q14: Can a Company for example be present via a satellite symposium, rent booth space at a Third Party Organised Educational Conference, which was assessed as non-compliant by the Conference Vetting System (CVS)?*

*A14: Please refer to Annex I for a detailed visual information of the scope of CVS and its impact on commercial activities.*

<sup>1</sup> For scope of application of CVS please refer to: <http://www.ethicalmedtech.eu>



### c. Satellite Symposia

Companies may purchase satellite symposia packages at Third Party Organised Educational Conferences and provide presentations on subjects that are consistent with the overall content of the Third Party Organised Educational Conference. Companies may determine the content of these satellite symposia and be responsible for Faculty selection.

*Q15: Can Companies directly support attendance by Healthcare Professionals engaged to speak only at satellite symposia at Third Party Organised Educational Conferences, e.g. registration fee, travel and/or accommodation?*

*A15: Companies must ensure that interaction with Healthcare Professional complies with the Code, including entering into a permissible service agreement with Healthcare Professionals engaged to speak at satellite symposia. The service agreements may provide for reimbursement of travel and/or accommodation costs necessary for delivering the Faculty services. Where payment of a registration fee is required in order for Faculties to access satellite symposia, Companies may also pay for the registration fee.*

### 2. Third Party Organised Procedure Training

Companies may support Third Party Organised Procedure Training via Educational Grants (in accordance with Chapter 4: Charitable Donations and Grants) in accordance with the following rules:

- Financial support must comply with the criteria provided in Chapter 1: General Criteria for Events.
- The Third Party Organised Procedure Training has been positively assessed via the Conference Vetting System, when applicable (see the Glossary)<sup>2</sup>.
- For financial support to Third Party Organised Procedure Training meetings, Companies must apply the requirements governing conduct and attendance at such events in the country where the Healthcare Professional carries on their profession and give due consideration to the requirements in the country where the event is being hosted.

*Q16: What are the main differences between Third Party Organised Educational Conferences and Procedure Trainings?*

*A16: Both Third-Party Organised Educational Conferences (see the Glossary) and Procedure Trainings (see the Glossary) are a type of Third Party Organised Educational Events. Therefore, they must comply with Chapter 1. General Criteria for Events; and, where applicable, are subject to the positive assessment in the Conference Vetting System (see the Glossary). For Third Party Organised Procedure Trainings the following three criteria shall apply:*

- *Programme: Unlike Third Party Organised Educational Conferences which are theoretical in nature, Third Party Organised Procedure Trainings consist of practical, hands-on trainings, generally involving more than one provider/manufacture/ sponsor.*

*This must be evident by the programme of the Event. The programme, which is often referred to as a "course", rather than a conference or seminar, must be focused on acquiring specific medical skills relevant to certain medical procedures (rather than products, or medical technologies). Examples may include courses aimed at acquiring or improving the Healthcare Professional's skills in minimally invasive surgery; orthopaedic trauma surgery; or the implantation of cardiac rhythm devices; etc.*

*The programme must also include practical demonstrations (and/or actual live surgeries, where allowed). Examples of practical demonstrations may include surgery simulations where technologies are used on cadavers; skin models; synthetic bones; in cath labs; etc.*

- *Venue: Third Party Organised Procedure Trainings are typically organised in a clinical environment, as opposed to, e.g., a classroom setting. For the avoidance of doubts, the adjective "clinical" includes places suitable for the simulation of medical procedures, rather than just the medical treatment of real patients.*

*Examples of clinical environment include hospitals or clinics, where medical treatment on real patients may be given; as well as conference rooms which are appropriately set up to simulate medical procedures, for example with the presence of medical technologies to be used on cadavers; skin models; synthetic bones; etc.*

- *Stand-alone nature of the event: Third Party Organised Procedure Trainings must stand-alone events. Where the majority of the Training is not given in a clinical environment, for example, where the Training is organised in connection, adjacent to or at the same time as a larger Third Party Organised Educational Conferences, that training will not qualify as a Third Party Organised Procedure Training, as*

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

defined in the Code.

*Q17: In the definition of Third Party Organised Procedure Training, what is meant by "Proctorship" and "Preceptorship"? Further, do Proctorships and Preceptorships require CVS approval before they can be provided and/ or supported by a Company?*

*A17: For the purposes of the Code both Proctorship and Preceptorship are types of clinician-to-clinician training funded by a Company. Proctorship is where the trainee clinician performs a procedure under the supervision of proctor clinician and where the trainee clinician has primary responsibility for the patient undergoing the procedure. Preceptorship is where the trainee clinician observes the procedural training of the trainer clinician who has a primary responsibility for the patient undergoing the procedure. Such Proctorships and Preceptorships normally take place on HCO premises and are not subject to CVS approval as it is not considered to be either a Third Party Organised Educational Event or a Third Party Organised Procedural Training.*

# Chapter 3: Company Events

## 1. General Principles

Company Events include, as defined in the [Glossary](#):

- Product and Procedure Training and Education Events
- Informational Meetings

Company Events should comply with the principles mentioned in [Chapter 1: General Criteria for Events](#).

Where there is a legitimate business purpose, Company Events may take place in Company's manufacturing plant or Healthcare Organisations, used by the Company as reference centres.

## 2. Product and Procedure Training and Education Events

Where appropriate, in order to facilitate the safe and effective use of medical technologies, therapies and/or services, Companies should make product and procedure training and education available to relevant Healthcare Professionals.

Companies shall ensure that personnel conducting the Product and Procedure Training and Education Events have the appropriate expertise to conduct such training.

*Q18: Is it appropriate for Companies to invite Healthcare Professionals on company plant or factory tours where the Healthcare Professionals reside outside the country of location of the plant or factory?*

*A18: It is appropriate for Companies to invite Healthcare Professionals to manufacturing site tours in countries outside their country of residence if there is a legitimate business purpose and the travel and accommodation reimbursement complies with the Code in all respects.*

*Q19: Can Companies directly support travel and/or accommodation or other expenses of individual Healthcare Professionals for attendance as delegates at Company Organised Events, happening before, during or after a Third-Party Organised Educational Event?*

*A19: No, Companies cannot directly support travel and/or accommodation or other expenses of individual Healthcare Professionals participating as delegates in Company Organised Events which take place before, during or after and in the same approximate location as a Third-Party Organised Event, as well as other Company Organized Events.*

*However Company Organised Events involving performance of services by the Healthcare Professionals including, for instance, advisory boards and clinical investigator meetings, may be organised within a Third Party Organised Educational Event for reasons of convenience and efficiency, given the attendance of Healthcare Professionals at that Third-Party Organised Educational Event. In such cases, the Company may still only pay for the contractual remuneration and expenses agreed for the provision of the services by the Healthcare Professional at the Company Event itself. Under no circumstances may a Company pay for incremental costs relating to the Healthcare Professional's who is a delegate on the Company Event, the Third Party Organised Educational Event, such as registration costs, hospitality, additional travel and/or accommodation. The Companies may be flexible in payment of travel costs, provided that this will not lead to additional costs (e.g. registration fees, hospitality, additional travel and/or accommodation) in comparison with basic scenario of Healthcare Professional participation in the Company Event only. Additionally, Healthcare Professionals must be active in such Company Events in accordance with the service agreement terms concluded with the Company and should not be just passive participants.*

*Q20: Under the Code, Chapter 3, Point 2, what is meant by "Company Organised Educational Event"?*

*A20: "Company Organised Educational Event" is a Company Event as defined in the Glossary, whose objective is genuine and bona fide medical education, and the enhancement of*



professional skills. "Educational" means communicating information directly concerning or associated with the use of Companies' medical technologies, e.g., information about disease states and the benefits of medical technologies to certain patient populations. In all cases the information and/or training must directly concern a Company's medical technologies, therapies and/or related services. This means that a Company must meet the following tests when organizing such an Event in order to be compliant with the IMEDA Code:

All Events must comply with the criteria of Chapters 1 and 3;

a) The programme must be strictly science- or education oriented. Its content must include current scientific information of a content and quality which is appropriate to the qualification and specialisation of Healthcare Professionals who are attendees at the Event.

b) The programme must be actually educational, and therefore sales and marketing objective cannot have a primary objective. This means that the Education part must fill most of the Program.

c) Information on the programme, clearly indicating the name of the Company organising the Event, should be made available in advance in order for invited Healthcare Professionals to be able to make a reasoned judgment as to the quality of the programme, provided that subsequent changes, deletions and additions to the programme are acceptable to the extent that such changes, deletions and additions are reasonable and do not significantly modify the quality and content of the programme.

d) The programme should in principle involve full days, with the majority of the morning and afternoon parts dedicated to scientific and/or educational sessions, unless the Event is a half day event, commences or ends on a midday or lasts less than half a day. Such half-day or less sessions are permissible, but there should not be any non-scientific or non-educational events or activities organized for the other part of the day. Furthermore, there should be no significant gaps in the programme which would permit Healthcare Professionals to engage in non-scientific or non-educational activities.

**Q21: Are cruise ships or golf clubs appropriate venues for Product and Procedure Training and Education Events?**

**A21.** No. Cruise ships, golf clubs or health spas and venues renowned for their entertainment facilities are not appropriate venues and should not be used. Examples of appropriate venues include hospital, clinic or surgical centre laboratory, educational, conference venues, or other similar venues, including Companies' own premises or leased facilities, that are conducive to effective transmission of knowledge and "hands on" training.

**Q22: What criteria should a Company apply when considering a place as**

### 3. Information Meetings

Where it is appropriate, Companies may organise Information Meetings.

In addition to the principles laid down in the Chapter 3, Section 1, Information Meetings should also comply with the following more stringent requirements:

- Such meetings should, as a general rule, occur close to the Healthcare Professional's place of business;
- It is not appropriate for travel or accommodation support to be provided to Healthcare Professionals by Companies.

*a location of Product and Procedure Training and Education Events?*

*A22: If the participants are primarily of one Russian region, the venue should be in the specific region involved. If the participants are from multiple Russian regions, then a region affording ease of access for all participants should be chosen.*

*Q23: Can a Company use a meeting venue outside Russia?*

*A23: Yes, provided the participants arrive from multiple countries outside Russia. If the participants are primarily from within Russia, the venue should be in Russia. It is permissible to organize the Event for participants from Russia in European countries provided that this is economically and administratively reasonable and substantiated (e.g. selection of European training center as a venue). However, if the selected venue is outside of Europe, in such country selected (and the state, if the location is in the United States) is the residence of at least some of the participants of the Product and Procedure Training and Education Event.*

*Q24: Can Companies directly support travel and/or accommodation of individual Healthcare Professionals at Company Events, which include new product launches, even if only portable equipment or solutions are being demonstrated?*

*A24: Companies can not gratuitously support travel and/or accommodation of individual Healthcare Professionals to attend any Company Events.*

# Chapter 4: Grants and Charitable Donations

## 1. General Principles

- a. Grants and Charitable Donations (see the [Glossary](#)) shall not be contingent in any way on past, present or potential future purchase of the Company's products or services, their lease, recommendation or prescription, supply. It is important that support of charitable and/or philanthropic programmes and activities by Companies is not viewed as a price concession, reward to favoured customers or as an inducement to purchase, lease, recommend, prescribe, use, supply or procure Companies' products or services.
- b. A Company shall not provide Grants or Charitable Donations to individual Healthcare Professionals. Grants and Charitable Donations must be provided directly to the qualifying organisation under certain circumstances. Grants and Charitable Donations shall not be provided in response to requests made by Healthcare Professionals unless the Healthcare Professional is an employee or officer of the qualifying organisation and submits the request in writing on behalf of the qualifying organisation.
- c. The payment (or provision of other support) by way of any Grant or Charitable Donation shall always be made out in the name of the recipient organisation and shall be paid directly to the organisation. Grants or Charitable Donations must not be provided in the name of a specific Healthcare Professional. In addition, all Grants and Charitable Donations shall define the Company as the provider of the Grant or Charitable Donation.
- d. It must in all cases be lawful under laws and regulations applicable on the territory of the Russian Federation for the Grant or Charitable Donation recipient to receive and benefit from the particular type of Grant/Charitable Donation.
- e. Companies shall implement an independent decision-making and review process to identify, prevent and mitigate against potential corruption risks arising in connection with the provision of a Grant or a Charitable Donation to a prospective recipient. This process shall include a documented, prior evaluation of any associated risks and of the relevant information concerning the intended recipient organisation.
- f. All Grants and Charitable Donations must be appropriately documented by the Company.

*Q25: Under the General Principles in Chapter 4. Grants and Charitable Donations, what is meant by an "independent decision-making and review process"?*

*A25: In accordance with the Principle of Separation, an "independent decision-making and review process", is a process where the decision-making criteria are not primarily sales-driven and where the Company's sales function does not decide upon to provide a Grant or Charitable Donation or their approval. For example, such a process could be led by a Company's legal, finance or compliance functions. This process must operate within a robust governance framework and according to clear, consistent and transparent criteria for review and decision-making.*

Moreover, Grants and Charitable Donations shall only be provided in response to a written request submitted by the requesting organisation. Company may also publish a documented initiative with respect to the provision of the Grants. The written request must contain information sufficient for the objective evaluation of the Grant request made by requesting organisation. No Grant and/or Charitable Donation shall be provided until a written agreement documenting the terms of this is signed by both parties.

- g. This section of the Code (Chapter 4: Grants and Charitable Donations) is not intended to address the legitimate practice by Companies of providing lawful rebates, additional product and/or service offerings, including free of charge, or other comparable pricing incentive mechanisms (“special offers”) which are included in competitive and transparent centralised purchasing arrangements, such as, for example, tenders.

## 2. Charitable Donations

Companies may make unrestricted Charitable Donations for genuinely charitable or other philanthropic purposes. “Unrestricted” in this context means that Companies shall have no control over the final use of funds (or other support) they provide as Charitable Donations beyond general restrictions to ensure that the funds (or other support) are applied for charitable and/or philanthropic purposes.

Charitable Donations may be made only to charitable organisations or other non-profit entities which have charitable and/or philanthropic purposes as their main purposes and which are objectively engaged in genuine charitable or philanthropic activities.

Charitable Donations shall always be made in accordance with the general principles set out in Chapter 4: Grants and Charitable Donations.

Restricted Charitable Donations to non-profit hospitals may be permissible in case of confirmed Financial Hardship (see Glossary) is present, when Charitable Donations serve exclusively the benefit of the patient, are limited in value, or explicitly permitted by laws and regulations applicable on the territory of the Russian Federation.

This section of the Code (Chapter 4: Grants and Charitable Donations- Charitable Donations) is not intended to address legitimate commercial transactions by Companies in the form of leasing of stands or booth space at Third Party Organised Educational Events and/or at any conference or event organised by a charity or other philanthropic organisation. Such activity is considered to be part of Companies’ normal marketing activity. Companies should, however, always consider the appropriateness of the

*Q26: Under the Code, what is meant by “prior evaluation of any associated risks and of the relevant information” relating to a Grant or a Charitable Donation?*

*A26: Prior to deciding to provide a Grant or a Charitable Donation, the Company must evaluate the appropriateness of the award of the proposed Grant or Charitable Donation to the proposed recipient. Such an evaluation shall consider all the circumstances including, but not limited to, consideration of the legal status and structure of the requesting (i.e. prospective recipient) organisation as well as of the nature and scope of its activities and the terms and conditions to which the Grant or Charitable Donation will be subject. The evaluation shall be documented and shall be based on information available to the Company, such as information or documentation available from public sources.*

*For Educational Grants provided in relation to Third Party Organised Educational Events, this may also include information of how the funds have been applied by the recipient in relation to previous equivalent Events and whether funds have been spent in accordance with the terms and conditions of any previous Grant.*

*Q27: What does “sufficient information” mean where used in connection with documentation of Grants and Charitable Donations?*

*A27: The written request by a requesting organisation should include as a minimum a detailed description of the scope and purpose of the programme, activity or other project, for which a Grant or a Charitable Donation is requested. The request shall also contain a description of the potential recipient, its legal status and governance structure, and where relevant, a budget.*

*Q28: Under the Code, can a Company make a Charitable Donation to support the general running of hospital or other Healthcare Organisation?*

*A28: No, a Company cannot make available a Charitable Donation to support the general running of a hospital or other Healthcare Organisation. A Charitable Donation shall only be given to a legal entity or body which has charitable and/or philanthropic purposes as its main purposes. For the purpose of the Code and irrespective of the legal status of the entity, hospitals and Healthcare Organisations are considered to generally have healthcare support as their main purposes and accordingly are not generally considered to have charitable and/or philanthropic functions as their main purposes in this context. It is not therefore appropriate to provide Charitable Donations to support general running of such organizations.*

*Q29: Is it permissible for a Company to specify restrictions in relation to the final use of a Charitable Donation where a Company wishes its Charitable Donation to be applied as part of a specific aid programme or as part of the relief effort following a specific natural disaster, such as a major earthquake in a particular country?*

*A29: Under the Code it is not appropriate for a Company to set conditions or apply restrictions to the final use of a Charitable Donation which go beyond general restrictions to ensure that the funds (or other support) are applied for charitable and/or philanthropic purposes. Companies may therefore impose general restrictions concerning the final use, such as the relief of a specific disaster or emergency in a particular country (e.g. for use to aid reconstruction and/or reequipping of healthcare facilities following the earthquake in that country). However, Companies must take care that such general restrictions are not so specific that the Charitable Donation is no longer unrestricted. The Charitable Donation may not be misused or be perceived to influence through undue or improper advantages, purchasing decisions, nor should such Donation be contingent upon sales transactions or use or recommendation of Companies’ products*

location, venue and the general arrangements for any such events and the impression that may be created by such events in order not to bring the industry into disrepute.

*Q30: Is it permissible for a Company to make a Charitable Donation to a Healthcare Professional's designated charity in instances where the Healthcare Professional has requested the Company to do so in lieu of paying him a professional fee for the provision of services to the Company?*

*A30: No. Under the Code it is not appropriate for a Company to support the favourite charity of a Healthcare Professional in response to a request by that Healthcare Professional acting on his/her behalf irrespective of the underlying reasons. If the Healthcare Professional with whom the Company has concluded a service agreement, is a president or other officer authorized to request a donation on charity organization's behalf, personal request on substitution of the professional fee with the equal donation to the relevant charity organization is not considered as appropriate, since such request is not considered as a request from the charity organization. No exception can be made for sport events, such as payment of the registration charge to participate in a charity run.*

*Q31: Under the Code, may a Company make a Charitable Donation such as the purchase of a table of dinner invitations at a fundraising dinner or entries to participate in, or attend at, a fundraising sports or other event?*

*A31: Yes, Charitable Donations made by Companies may take the form of payments for dinner invitations for a fundraising dinner or participating in other recreational events such as a fundraising golf tournament, if arranged by a charitable or other non-profit philanthropic organisation. The Company may use some or all of its ticket allotment for its own employees and return any unused portion to the charitable or non-profit philanthropic organisation for use as the sponsoring organisation sees fit. However, the Company should not invite Healthcare Professionals to attend such an event at the Company's expense. Furthermore, the Company is not permitted to suggest to the organizer, the names of Healthcare Professionals who could be invited to attend the event, irrespective of whether or not the specified Healthcare Professionals will be seated at the Company's table.*

### 3. Educational Grants

Companies may provide restricted Educational Grants (see the [Glossary](#)) for the advancement of genuine medical education. "Restricted" in this context means that Companies shall specify the intended purpose of the Educational Grant in the Grant agreement. A Company shall also ensure that the Educational Grant agreement with the recipient organisation includes rights to enable it to verify that the Grant is in fact used for the agreed intended purpose. Educational Grant agreements qualify as donation agreements under Russian law, however, requirements to Charitable Donations set forth in the previous section of the Code (Chapter 4: Grants and Charitable Donations-Charitable Donations) are not applicable to them.

Companies shall document and publicly disclose all Educational Grants in accordance with the Code's Disclosure Guidelines, and publication shall commence no later than the end of the Transition Period.

Companies may provide Educational Grants for the following (non-exhaustive) purposes:



a. **Support for Third Party Organised Educational Events**

As a general rule, any Third Party Organised Educational Event supported by way of an Educational Grant from a Company to a non-commercial Healthcare Organisation must:

- Comply with Chapter 1. General Criteria for Events; and
- Where applicable, have positive assessment via the Conference Vetting System (see the [Glossary](#))<sup>3</sup>

*Q32: Can a small sized Healthcare Organisation (HCO) receive Educational Grants to support Healthcare Professionals participation at Third Party Organised Educational Events?*

*A32: Yes, in principle. There are no size limits for HCOs to receive Educational Grants; however, Companies must ensure that the final beneficiaries of the Educational Grant cannot be defined beforehand. For example, HCOs composed of a single Healthcare Professional will in practice not be allowed to receive Educational Grants to support Healthcare Professionals participation at Third Party Organised Educational Events, as the final beneficiary is known upfront.*

*Q32-bis: Can an Educational Grant or funds earmarked for education be provided to a specific hospital or department or specify individual hospital or department as criteria for HCOs and/or PCOs?*

*A32-bis: One of the guiding principles in the Code is that companies should not receive or be able to determine the names of the ultimate HCP beneficiaries. However, the inclusion of a criterion specifying an individual hospital or hospital department is not prohibited under the Code. However, Companies should bear in mind that the smaller the hospital or department the greater will be the risk that Companies will be able to circumvent this restriction and to use such a criterion inappropriately under the Code. In addition, companies should be mindful of any proximate or ongoing tender proceedings with that specific hospital, as such tenders may raise additional red flags.*

1) **Support for HCP Participation at Third Party Organised Educational Events:**

Where the Educational Grant is provided for the purpose of supporting Healthcare Professionals' attendance at Third Party Organised Educational Events, the Healthcare Organisation receiving the Grant shall independently select participants and this shall be expressly reflected in the written Grant agreement.

*Q33: How can Companies in practice ensure that Educational Grants made available for Third Party Organised Educational Events which are subject to the Conference Vetting System, are positively reviewed by CVS?*

*A33: It is the responsibility of Companies to ensure compliance with this Code obligation. For example, Companies may themselves submit relevant Third Party Organised Educational Events for CVS review, they may include appropriate contractual obligations making it a pre-condition for an Educational Grant that the Third Party Organised Educational Event be submitted and positively assessed via the CVS by the prospective Grant recipient or by a third party.*

*Q33-bis Can Companies give criteria for HCOs and/or PCOs to allocate their Educational funds?*

*A33-bis: Yes, it is permissible to set objective criteria for a HCOs and/or PCOs which are non-commercial organizations to select HCPs to benefit from Educational funds may be given as long as such selection criteria are relevant to the HCPs' educational needs and are not so specific that it would effectively select individual HCPs. Examples of criteria for selecting Educational Grant ultimate beneficiaries are Healthcare Professionals' specialty, years of practice, country, city/region of practice and/or scientific achievements such as number of publications, participation in clinical trials in a given pathology.*

<sup>3</sup> For scope of application of CVS please refer to: <http://www.ethicalmedtech.eu>

## 2) Support for Third Party Organised Educational Events:

Where the prospective beneficiary of an Educational Grant is the organiser of the Third Party Organised Educational Event and is also a Healthcare Organisation, the recipient Healthcare Organisation shall be solely responsible for:

- The programme content;
- The selection of Faculty; and
- The payment of Faculty honoraria, if any.

Companies shall not have any detailed involvement in determining the content of the educational programme and selection of Faculty (see [Glossary](#)) and this shall be reflected in the written Grant agreement. If expressly requested to do so, Companies may recommend Speakers or comment on the programme content if specifically requested by organizers.

*Q34: Is it appropriate for a Company that has provided an Educational Grant to support Healthcare Professional attendance at a Third Party Organised Educational Event to receive the names of the Healthcare Professionals benefiting from the Educational Grant?*

*A34: A Company should not proactively seek to receive the names of the Healthcare Professionals benefiting from its Educational Grant. Generally, when a Third Party Organised Educational Event is supported by more than one company, all companies should receive the same attendance list, from which it should not be possible to identify which Healthcare Professionals have benefited from a particular Company's Educational Grant.*

*For purposes of auditing, compliance and monitoring by relevant Company, it may be necessary for a Company to request and receive the names of the Healthcare Professionals who have benefited from the Educational Grant provided by the Company after the Event has taken place.*

*In this case, unless required by law, such Healthcare Professional names should never be received by the Company until the Educational Grant agreement has been signed and the independent selection process of the Healthcare Professionals has been completed and in strict compliance with the applicable legislation on personal data.*

*Q35 Does Chapter 4: Donations and Grants – Educational Grants of the Code apply to requests received by Companies in the context of public procurement processes for educational support for Third Party Organised Educational Events from Healthcare Organisations and purchasing bodies?*

*A35: No. Such requests and any subsequent financial or other support provided by a Company are not considered to be Educational Grants for the purpose of the Code. Such arrangements are commercial in nature and not philanthropic and should be documented in a written commercial agreement in accordance with normal business practice.*

*Q36: In the event that a commercial organisation, such as a Professional Conference Organiser (PCO), organises a Third Party Organised Educational Event independently of any Healthcare Organisation (HCO), is it appropriate for Companies to sponsor such events and what rules shall apply?*

*A36: Companies may enter into a commercial sponsorship arrangement with a Professional Conference Organiser organising a Third Party Organised Educational Event independently of any Healthcare Organisation. However, such arrangements do not fall within the definition of Educational Grant as Professional Conference Organiser are generally for-profit organisations. Sponsorship arrangements are therefore commercial in nature and Companies should consequently document these in a written commercial agreement in accordance with normal business practice and the requirements of the Code (Chapter 2: Third Party Organised Educational Events). In addition, a Company cannot provide funds earmarked for the advancement of genuine educational purposes to a for-profit Professional Conference Organiser. Provision of such funds is possible to a non-profit Professional Conference Organiser, acting independently of any Healthcare Organisation, all the Code provisions governing Educational Grants shall be observed. For example, if a Company provides funding to a non-profit Professional Conference Organiser to fund Healthcare Professional delegate places and expenses at a Third Party Organised Educational Conference, such Event, where applicable, must have CVS approval and the Company shall publicly disclose such funding in accordance with the Code's Disclosure Guidelines.*

#### b. Scholarships and Fellowships

Companies may provide Educational Grants with restricted purposes in the form of Grants for Scholarships and Fellowships to support advancement of genuine medical education of Healthcare Professionals (see the [Glossary](#)). Only Healthcare Organisations where Healthcare Professionals are in training shall be eligible to request and/or receive such Educational Grants.

A Company shall not provide Educational Grants to support Scholarships and Fellowships upon request of individual Healthcare Professionals. Similarly, the Company shall not have any involvement in any way in the selection of the HCPs who will benefit from the Educational Grant and this shall be reflected in the written Grant agreement between the Company and the recipient HCO.

*Q37: Can a Company pay for or reimburse travel costs to a Third Party Organised Educational Event for a Scholar or Fellow?*

*A37: No, a Company cannot additionally pay for, or reimburse, the travel or other participation costs incurred by a Healthcare Professional who received the Scholarship or Fellowship Grants with respect to their attendance to a Third Party Organised Educational Event. Such costs shall be included in the Educational Grant in a form of the Scholarship or Fellowship if it is intended that the Grant should extend to such attendance.*

#### c. Grants for Public Awareness Campaigns

Companies may also provide Educational Grants with restricted purposes to Healthcare Organisations for the legitimate information distribution, promoting awareness and/or educating patients, carers or the general public about relevant healthcare topics or medical conditions or diseases in therapeutic areas in which the Company is interested and/or involved.

*Q38: Can Companies finance professional training of Healthcare Professionals on general medical education topics, such as courses on health economics/health technology appraisal, good laboratory practice or similar topics that promote patient care?*

*A38: Companies can support genuine medical education for Healthcare Professionals on general healthcare-related topics through Educational Grants in accordance with Chapter 4 of the Code.*

*Companies can also support genuine medical training on general healthcare related topics through company-organised "Product and Procedure Training and Education Events" as long as the information directly concerns the Company's medical technologies, therapies, and/or related services. The Event must be conducted in accordance with requirements of, Chapter 3, Section 2 of the Code.*

*Q39: What are examples of relevant appropriate disease and healthcare education for patients, carers and the general public for which a Company may legitimately provide an Educational Grant?*

*A39: A Company may provide an Educational Grant to support the provision of high quality information to patients and the public about health and disease provided there is an objective patient or public need for such information and the topics covered are linked to the therapeutic areas in which the Company is interested and/or involved. Such disease awareness campaigns must not, however, promote the use of particular therapies, services or promote specific HCOs, nor may they aim to stimulate demand by the public for specific therapies or for specific Healthcare Organisations.*

#### 4. Research Grants

*Q39-bis Can a Company support the participation of the poster-speaker Healthcare Professionals in the Third Party Organised Educational Event?*



Where permitted by laws and regulations applicable on the territory of the Russian Federation, Companies may provide Research Grants (see the Glossary) with restricted purpose for use to support clearly defined third party-initiated research studies for clinical or non-clinical research programmes in therapeutic areas in which the Company is interested and/or involved. Research Grants may include in kind or financial support for legitimate, study-related, documented expenses or services, and/or reasonable quantities of single-use and/or multiple-use free of charge product(s) for the limited duration of the research. Research Grant agreements qualify as donation agreements under Russian law, however, requirements to Charitable Donations set forth in Section 2 of Chapter 4 of the Code (Chapter 4: Grants and Charitable Donations- Charitable Donations) are not applicable to them.

Companies providing Research Grants shall ensure that they do not influence the research. However, in order to ensure that Research Grants are provided on a "restricted" basis, Companies shall clarify the intended research scope and purposes for which the Grant is requested and shall ensure that the written Grant agreement with the recipient organisation includes rights for the Company to verify that the Grant is applied solely for the agreed intended research use. Such verification may include a request for study-related documentation, such as a copy of the research protocol, a copy of the ethics committee and/or regulatory approvals or a copy of the study report upon completion or earlier termination of the research.

All requests for Research Grants from prospective Grant beneficiaries must be in writing and must detail, as a minimum, the type, nature and objectives of the research activity, the milestones and budget, the approximate duration of the research, and where applicable, the requirements for ethics committee, regulatory and/or other authorisations or approvals.

A Company may give consideration to a request for a Research Grant prior to ethics committee approval for the specific research project but shall not take any final decision regarding the Grant request unless and until the research receives formal ethics committee approval.

Research Grant agreements shall include provisions relating to adverse event reporting where appropriate, and shall require full disclosure of the Company and of the Grant by the Grant recipient organisation and by the lead-investigator in all oral or written presentations of the results.

For guidance on how Companies may undertake Company-initiated research please refer to Chapter 6: Research: Company-Initiated Research.

*A39-bis Poster-speakers in the Third Party Organised Educational Event are not covered by the Faculty definition in accordance with the Glossary. Therefore, if the Company wishes to support the participation of such Healthcare Professionals in the Third Party Organised Educational Events, this support may be provided as an Educational Grant (if this complies with this Code, including Chapter 4). As an alternative, such support may be provided as a part of the third party or Company initiated research agreements.*

*However, if this support is a part of the research agreement, Companies may support the poster-speakers only if the following conditions are met:*

- Poster-speaker Healthcare Professionals are selected independently by the third party organiser;*
- Anticipated support is specified in the relevant research agreement between the Company and Healthcare Organization;*
- Company does not directly participate in the selection of the specific researchers, which will be ultimate beneficiaries of the provided support (for avoidance of doubt, the principal investigator with whom the Company may have direct relationship, has a right to receive support for dissemination of research results).*

*Companies should also include into the research agreements the provisions approving the use of the provided support funds only after independent selection of the Poster-speaker Healthcare Professional by the third party organiser.*

# Chapter 5: Service Arrangements

## 1. General Principles

Companies may engage Healthcare Professionals in relation to clinical studies of medical devices and for performance by Healthcare Professionals of pedagogic and(or) scientific activity (service arrangements). Companies may pay Healthcare Professionals reasonable remuneration for performing these services. In all cases, service arrangements must be permitted under the laws and regulations of the country where the Healthcare Professional conducts the medical activities.

The principles in this chapter are applicable to all service arrangements between Healthcare Professionals and Companies including where a Healthcare Professional service provider declines a fee for provision of their services.

Service arrangements shall not be contingent in any way on the prospective service provider's past, present or potential future sales or purchase, lease, recommendation, prescription, or use of the Company's products or services.

When selecting service providers, Companies shall implement an independent decision-making and review process to identify, prevent and mitigate against potential corruption risks arising in connection with use of service providers. This process shall include a documented, prior evaluation of any such associated risks and of the relevant background information concerning each prospective service provider.

## 2. Criteria for service arrangements

In addition to the general principles above, the arrangements which cover services to be rendered must, to the extent applicable to the particular arrangement, fulfil all the following criteria:

- a. Service arrangements must be entered into only where a legitimate business need for such services is identified in advance.
- b. The number of service providers retained must not be greater than the number reasonably necessary to achieve the identified need.
- c. Selection of service providers must be based on criteria directly related to the identified business need and the relevance of the service provider's qualifications, expertise and experience to address the identified need. The volume or value of business generated by a prospective service provider or the Healthcare Organisation where

she/he performs her/his professional activity is not an applicable criterion.

- d. Service arrangements with Healthcare Professionals must be documented in a written agreement, signed by the parties in advance of the commencement of such services, which must specify the nature of the services to be provided and the basis for payment for those services.
- e. The hiring of the service provider must not be an inducement to purchase, sale, lease, recommend, prescribe or use the Company's products or services.
- f. The remuneration for the services rendered must be reasonable and be in line with the fair market value of the services provided.
- g. Companies must maintain documented records of the services, and associated work products, provided by the Healthcare Professionals service providers and documented records of the use made of those services by the Company.
- h. The venue and other arrangements (e.g. hospitality, travel etc.) for purposes of engagement of service providers in Company events shall follow the rules for Events set out in Chapter 1: General Criteria for Events.

### 3. Remuneration and Fair Market Value

The remuneration paid to Healthcare Professionals engaged as service providers by Companies shall be in line with fair-market-value for the services provided. It shall not be in any way contingent upon the value of products or services which service providers may purchase, lease, recommend, prescribe, use, supply or procure in the course of their own professional practice or that may be purchased, leased, recommended, prescribed, used, supplied or procured by HCOs where they carry on their professional activities.

All payments made for services must comply with all applicable tax and other legal requirements. Companies may pay for expenses reasonably incurred by service provider in providing the services which are the subject of the respective service arrangement including reasonable travel, meals and accommodation expenses incurred by service provider. The written service agreement must detail which expenses are to be reimbursed to the service provider in relation to the provision of the services and the basis for reimbursement of these by the Company.

### 4. Disclosure and Transparency

Companies shall ensure they fully comply with all laws and regulations applicable on the territory of the Russian Federation requiring any publication, disclosure or approval in connection with the use by Companies of Healthcare Professionals as service providers.

Companies shall maintain appropriate transparency by requiring the relevant Employer Notification (as defined in the Glossary) which shall disclose the subject and terms of the service arrangement is made prior to performance of the service arrangement.

Companies shall also include contractual obligations on the service provider to ensure the disclosure of the information

*Q40: What is meant by fair market value (FMV) in the context of service arrangements?*

*A40: Fair-market-value is the value of the specific services which would be paid by the Company to the service provider, provided that each dealing at arm's length in an open and unrestricted market, and when neither party is under any compulsion to enter into transaction, and both parties have reasonable knowledge of all facts.*

*Q41: How should Companies determine FMV for a service?*

*A41: A Company must be able to demonstrate internal methodology to determine fair market value. Amongst other matters this shall take account of the service provider's qualifications, expertise and experience as well as the actual services to be provided to the Company.*

*Q42: Under the Code, is Employer Notification required for each interaction with a Company?*

*A42: Employer Notification is required whenever a Company engages a Healthcare Professional in accordance with the permitted service agreement, but not required for each interaction with the Healthcare Professional within this agreement.*

*Q43: Are Companies required to provide details of the costs Companies will bear with regard to the Healthcare Professional engagement for the service provision in the Employer Notification?*

*A43: Companies are not required to provide details of the costs Companies will bear with regard to the Healthcare Professional engagement for the service provision in the Employer Notification. . Under the Code, Companies must ensure that the level of remuneration is commensurate with*

on the service provider's participation as a counterparty for the Company in the research for, or the preparation of, material for scientific publication of any publication or presentation.

*the services provided and not greater than a fair market value. However, the purpose of the Employer Notification is to provide transparency on the nature of the interaction between the Company and the Healthcare Professional and to enable the employer to raise objections if they perceive a potential conflict or have other issues concerning the interaction.*

# Chapter 6: Research

## 1. Company-Initiated Research

Where there is a legitimate business need, Companies may initiate, conduct, manage and finance scientifically valid research to generate necessary data, whether pre- or post-market. In this context, legitimate business needs for data include medical needs, including patient safety; research and development; scientific purposes (e.g. performance indicators, comparing objective scientific parameters); regulatory, including post-market surveillance (PMS) and post market clinical follow up (PMCF), vigilance, safety, or reimbursement and health economic, including clinical and cost-effectiveness and outcomes data relevant to health technology assessments (HTA) and reimbursement decision-making.

Where a Company uses a Healthcare Professional as a service provider, for example to lead a study on the Company's behalf (i.e. act as Principal Investigator), the Company shall ensure that such service arrangements comply fully with Chapter 5: Service Arrangements.

In accordance with the Documentation Principle, any arrangements made by a Company to procure research-related services shall be set out in a written agreement which shall reference a written research protocol; written schedule of work and provide for all required consents, approvals and authorisations to be obtained prior to the commencement of the study.

Companies must ensure that their research activities comply with all applicable laws and regulations applicable on the territory of the Russian Federation, as well as with applicable Good Clinical Practice guidelines, if relevant.

In accordance with the Principles set out in the Introduction: Aims and Principles of the Code, Companies shall also ensure appropriate clinical trial transparency in relation to their research activities and results. This shall include relevant disclosure of information about Companies' clinical trials, for example in external public registries and peer-reviewed journals.

Where Companies engage third party intermediaries for research (e.g. contract research organisations (CROs)), they shall ensure that the research conducted by these third parties on behalf of the Company is carried out in accordance with all applicable legal and ethical requirements, including the applicable requirements of the present Code.

## 2. Company Post-Market Product Evaluation

*Q44: What is an example of an external public registry for clinical trial transparency?*

*A44: Examples of an external public register for clinical trial transparency are [www.clinicaltrials.gov](http://www.clinicaltrials.gov) or [www.who.org](http://www.who.org)*

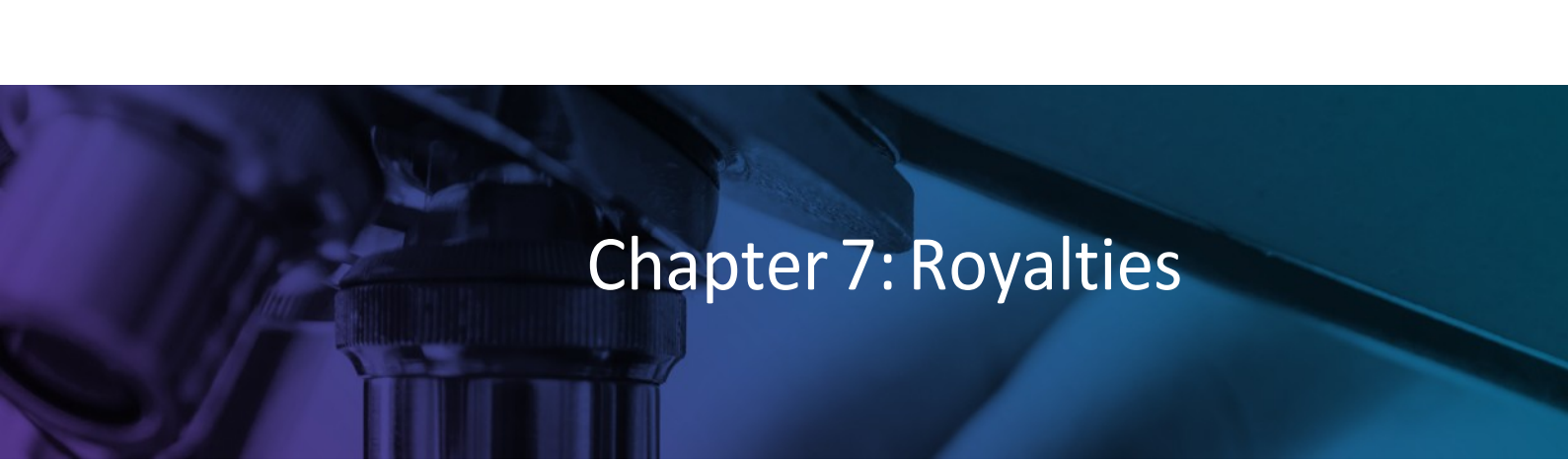
Where there is a legitimate business need, Companies may initiate post-market third party evaluation of their products, therapies and/or related services and may therefore provide Evaluation Products under a written contract for services in order to obtain defined user evaluation by Healthcare Organisations in relation to the Evaluation Products. Evaluation Products may be provided to the Healthcare Organisation within a concluded service agreement on product evaluation. The evaluation results must be formalized in a protocol or questionnaire forming an integral part of such contract.

Where the Evaluation Products are multiple-use Evaluation Products the defined period of time necessary for the evaluation and feedback to occur will depend on the frequency of anticipated use; the nature of the user evaluation feedback requested; the duration of any required training and similar considerations. Companies shall in all cases ensure that they retain title to multiple use Evaluation Products and that they have a process in place for promptly removing such multiple use Evaluation Products and/or any unused single-use Evaluation Products from the Healthcare Organisation's location at the conclusion of the evaluation period unless these are purchased by the Healthcare Organisation.

Provision of Evaluation Products and/or related services must not improperly reward, induce and/or encourage Healthcare Professionals and/or Healthcare Organisations to purchase, lease, recommend, prescribe, use or supply Companies' products or services. Any offer and/or supply of Evaluation Products shall always be done in full compliance with laws and regulations applicable on the territory of the Russian Federation.

### **3. Third Party-Initiated Research**

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



## Chapter 7: Royalties

Companies may not enter into a separate arrangements with Healthcare Professionals on remuneration for the Company's use of the rights for the intellectual property owned by the Healthcare Professional (royalty). In case royalty payment is a part of a service arrangement, Company shall ensure that such service arrangements comply fully with Chapter 5: Service Arrangements.

# Chapter 8: Educational Items and Gifts

Companies may not gift educational items and/or gifts to Healthcare Professionals. Companies may temporarily provide to the Healthcare Professionals materials necessary for the purposes of the event (for example, coats), which should be returned once the event has ended.

*Q45: Is it acceptable for the Company to provide to the Healthcare Professionals stationery and other materials for the purposes of the events?*

*A45: Companies may provide to the Healthcare Professionals for the purposes of the events stationery (writing pads, pens, pencils) of nominal value and information materials of nominal value.*



# Chapter 9: Demonstration Products and Samples

## 1. General Principles

Companies may provide their own products as Demonstration Products and/or Samples (see the [Glossary](#)) at no charge in order to enable Healthcare Organisations to evaluate and/or familiarise themselves with the safe, effective and appropriate use and functionality of the product and/or related service, as well as to determine whether, or when, to use, order, purchase, prescribe or recommend the product and/or service in the future.

Demonstration Products and/or Samples may be either single- or multiple-use products. Companies may also provide products from another company in conjunction with the Company's own Demonstration Products and/or Samples on an exceptional basis if those other company's products are required in order to properly and effectively demonstrate, evaluate or use the Company's products, e.g. computer hardware and software produced by an organization other than the Company.

Provision of Demonstration Products and/or Samples must not improperly reward, induce and/or encourage Healthcare Professionals and/or Healthcare Organisations to purchase, lease, recommend, prescribe, use or supply Companies' products or services. Any offer and/or supply of such products shall always be done in full compliance with the Code, laws and regulations applicable on the territory of the Russian Federation.

Companies shall in all cases maintain appropriate records in relation to the provision of Demonstration Products and/or Samples to Healthcare Organisations, for example recording proof of delivery for any Demonstration Products and/or Samples provided and receipt of return for multiple-use Demonstration Products and/or Samples. Companies shall clearly record in the Company's records as well as clearly disclose to Healthcare Organisations the no-charge basis and other conditions applicable for the provision of such Demonstration Products and/or Samples no later than the time of the provision. The disclosure to Healthcare Organisations shall be in writing.

This Chapter is limited to the provision of Demonstration Products and/or Samples and related services at no charge and is not intended to apply to provision of products or related services under any other arrangements, for example (but not limited to) provision within the framework for clinical trials and/or other research or commercial supplies by way of pricing incentives in a public procurement context.

## 2. Demonstration Products (Demos)

Companies may provide demonstration examples of their products to Healthcare Organisations in the form of mock-ups (such as unsterilized single use products) that are used for Healthcare Professionals and patient awareness, education and training. For example, a Healthcare Organisation may use a Demonstration Product to show a patient the type of technology which will be implanted in the patient or may use the Demo to train Healthcare Professionals in the use of the product.

Demonstration Products are not intended for clinical use in any patient care nor are they intended for on-sale or other transfer. Companies shall clearly record in the Company's records as well as clearly disclose to Healthcare Organisations the no-charge basis and other conditions applicable for the supply of such Demonstration Products no later than the time of the supply. It is recommended that the disclosure to Healthcare Organisations be in writing.

## 3. Samples

Companies may provide a reasonable number of Samples at no charge to allow Healthcare Organisations to familiarise themselves with the products and/or related services, to acquire experience in dealing with them safely and effectively in clinical use and to determine whether, or when, to use, order, purchase, prescribe or recommend the product and/or service in the future.

For Samples, which are single-use products, the quantity provided for purposes of familiarisation must not exceed the amount reasonably necessary for the Healthcare Organisation to acquire adequate experience in dealing with the products.

For Samples, which are multiple-use products, the specific length of time necessary for a Healthcare Organisation to familiarise Healthcare Professionals with the product will depend on the frequency of anticipated use; the duration of required training; the number of Healthcare Professionals who will need to acquire experience in dealing with the product and similar considerations. Companies shall in all cases ensure that they retain title to multiple use Samples and that they have a process in place for promptly removing such multiple use Samples from the Healthcare Organisation's location at the conclusion of the familiarisation period.



## PART 2: Disclosure Guidelines

## Preamble

Under the IMEDA Code of Ethical Business Practice (the “Code”), Companies are permitted to support independent medical education of Healthcare Professionals, including their participation in Third Party Organized Educational Events through the provision of Educational Grants to Healthcare Organisations in compliance with the rules set out in the Code. To prevent abuses, specific safeguards when providing Educational Grants have been developed, including the obligation to disclose these Educational Grants.

Accordingly, Section 3 of Chapter 4 of the Code states that Companies shall document and publicly disclose all Educational Grants in accordance with these Disclosure Guidelines. These Disclosure Guidelines are therefore an integral part of the Code, and need to be applied as such.

For the avoidance of doubt, all funds provided by a Company for the advancement of genuine educational purposes to a Professional Conference Organiser (“PCO”), acting independently of any Healthcare Organisation, fall under the scope of these Disclosure Guidelines and are subject to the same conditions as Educational Grants. Whenever these Disclosure Guidelines refer to Healthcare Organisations, these also include Professional Conference Organisers.

All capitalised concepts used in the Guidelines are concepts defined in the Code.

# Chapter 1: Applicability of these Guidelines

## 1. Scope

These Disclosure Guidelines (the "Guidelines") apply to Companies in their interactions with Healthcare Organisations based or registered in Russian Federation.

Separate entities belonging to the same multinational company ("Affiliates") - which could be the parent company (e.g. the headquarters, principal office, or controlling company of a commercial organization), subsidiary company or any other form of enterprise or organisation - shall be deemed to constitute a single company, and are as such committed to compliance with these Disclosure Guidelines.

The Guidelines shall not apply to the transfers of value that are not included in the definition of Educational Grants (as described in Chapter 4, Section 3 of the Code) and that consequently cannot be allocated to any of the categories set forth in Section 2.2 Aggregate Disclosure.

*Q1: Does the Disclosure Guideline's definition of "Affiliate" include legal entities belonging to the same parent Company but registered outside Russia?*

*A1: Yes. Educational Grants made by Affiliates (only subsidiary companies are included in the definition of Affiliates to the effect of the Disclosure Guidelines) incorporated outside of Russian Federation to Healthcare Organisations registered in Russian Federation are within the scope of these Disclosure Guidelines. Any of the Affiliates registered in Russian Federation can disclose these Educational Grants. Each Company can choose which Affiliate will report these Educational Grants made by Affiliates.*

*Q2: Are these Disclosure Guidelines applicable to third party intermediaries who interact with Healthcare Organisations in connection with the sale, promotion or other activity involving Companies' products?*

*A2: No, these Disclosure Guidelines are not applicable to third parties such as third party sales & marketing intermediaries (SMIs), consultants, distributors, sales agents, marketing agents, brokers, commissionaire commercial agents and independent sales representatives (list not exhaustive). Nevertheless, it is recommended to document arrangements concluded between Companies and third parties intermediaries in order to comply with the provisions set out in the Code. However the formalization of agreements between Companies and third-party intermediaries in a document is recommended to ensure compliance with the Code.*

## 2. Applicability of these Disclosure Guidelines

Companies are not obliged to report the same information twice due to being bound by laws and regulations applicable on the territory of the Russian Federation and imposing disclosure obligations regarding Educational Grants (as described in Chapter 4, section 3 of the Code) equivalent to the ones imposed by these Disclosure Guidelines (is applicable by reference to the provisions of paragraph two of Chapter 3, Point 5).

# Chapter 2: Disclosure Obligation

## 1. General Obligation

Subject to the terms of these Disclosure Guidelines, each Company shall document and disclose all payments related to Educational Grants (as described in Chapter 4, section 3 of the Code) that it makes to a Healthcare Organisation based or registered in Russian Federation, without limitation of value.

Educational Grants provided by Company Affiliates which are registered outside the MedTech Europe Geographic Area must be disclosed in accordance with these Disclosure Guidelines by such Company Affiliate registered in the MedTech Europe Geographic Area.

## 2. Aggregate Disclosure

Educational Grants shall be disclosed on an aggregate basis. Each Company shall disclose, for each clearly identifiable and separate recipient, the amounts paid as Educational Grants to such recipient in each Reporting Period<sup>4</sup> which can be reasonably allocated to one of the categories set out below. Such amounts will be aggregated on a category-by-category basis, but itemised disclosure shall be made available upon request by the Company, as deemed necessary, to (i) the relevant recipient, and/or (ii) the relevant authorities.

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

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

## 3. Optional Object Specification

If desired, Companies may indicate the object of the Educational Grants disclosed for one or both categories set forth in *Section 2.2* Aggregate Disclosure.

*Q3: Which Affiliate should disclose a particular Educational Grant?*

*A3: The Company may use any internal procedure allowing the disclosure of aggregate Educational Grants amounts provided to individual HCOs by all entities of the Company's group (Affiliates).*

*To facilitate the Educational Grants disclosure procedure it is recommended that the Company disclose using one user account. However, Companies can make disclosure using different user accounts for each Affiliate.*

*Q3-bis: Shall the disclosed amount be inclusive of VAT?*

*A3-bis: No, the disclosed amount must be exclusive of VAT, even if the VAT has been paid.*

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<sup>4</sup> Reporting Period means a full calendar year (starting on the 1st of January and ending in the 31st of December).

## 4. Methodology

Each Company shall create a note summarising the methodologies used by it in preparing the disclosures and identifying Educational Grants for each category described in Section 2.2 Aggregate Disclosure. The note, including a general summary and/or country specific considerations, shall describe the recognition methodologies applied, and should include the treatment of VAT and other tax aspects, currency aspects and other issues related to the timing and amount of Educational Grants for purposes of these Disclosure Guidelines, as applicable. This methodology note shall be made available upon request by an interested party.

*Q 4: When should a Methodology Note be made available?*

*A4: Companies should create a comprehensive Methodology Note that would allow any Healthcare Organisation directly affected by a disclosure to understand how the amount disclosed was calculated. The Methodology Note should therefore be made available upon specific request to Healthcare Organisations concerned about a particular disclosure that directly affects them.*

*Q 4-bis: In accordance with Guidelines, are in-kind Educational Grants subject to disclosure?*

*A4-bis: In-kind Educational Grants and other in-kind educational activities support, including Samples and Demonstration Products are not subject to disclosure.*

# Chapter 3: Form of Disclosure

## 1. Reporting Period

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

*Q5: When will the first Reporting Period start?*

*A5: The Transition Period ends on the 31st December 2020. As a consequence, the first Reporting Period is the calendar year 2021, starting on the 1st January 2021, and ending on 31st December 2021.*

## 2. Time of Disclosure

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

## 3. Time of Publication

Disclosures are made public at the time of publication. The time of publication on the Company's website is until 1st of July of the year following the Reporting Period. If the Company provides the disclosure information for the publication on the IMEDA web-site, this information must be provided to IMEDA before 1st of July, and the publication on the IMEDA web-site is made before 31st of August of the year following the Reporting Period.

## 4. Template and Language of Disclosure

For consistency purposes, disclosures made pursuant to these Disclosure Guidelines shall be made in Russian using the template set forth in the Annex.

*Q6: In what currency should the amounts payed be disclosed?*

*A6: Disclosed amounts should be in the currency used in the payment. In the event the aggregate amount includes Educational Grants made in different currencies, the reporting company may choose in which currency they wish to disclose the aggregate amount, and keep appropriate record of the exchange rate used to convert the different currencies. This information will then be included in their Methodology Note.*

## 5. Platform of Disclosure

The Company discloses the information via publication on its websites, if this is not possible - the relevant information must be provided for publication on IMEDA website. For the avoidance of doubt, IMEDA shall not be held liable for credibility of the data contained in the information published on the IMEDA web-site and provided by the Company.

If the Company has disclosed such information earlier in other sources (e.g., on EthicalMedTech website), it is not obliged to make a repeated disclosure of this information. However, it shall place corresponding link to this earlier disclosure on its website or provides this link for placement on IMEDA web-site.

## 6. Retention and Modification of the Disclosures

Companies shall be able to modify, delete or in any way alter their disclosures at any time before or after the time



of publication.

The information disclosed shall remain in the public domain for 3 years after the time such information is first published.

## **7. Enquiries Regarding Reported Disclosures**

Companies shall make available to Healthcare Organizations upon request any data concerning their common contractual relations published in accordance with these Disclosure Guidelines at any time while the disclosed information remains in the public domain as stated in Section 3.3 Time of Publication.



## PART 3: Glossary

# Glossary and Definitions

- **Charitable Donations:** provision of cash, equipment, company product or relevant Third Party product, for exclusive use for charitable or philanthropic purposes and/or to benefit a charitable or philanthropic cause.
- 
- **Company Events:** activities of any type that are planned, budgeted, managed and executed in whole or in part by or on behalf of Companies to fulfil a legitimate, documented business need of the Company, including but not limited to a legitimate business need to interact with customers including Healthcare Professionals and/or Healthcare Organisations.
- 
- **Conference Vetting System (CVS):** the centralised decision-making process with respect to the compliance of Third Party Organised Educational Events with the Code and which is managed independently of MedTech Europe under the supervision of the MedTech Europe Compliance Panel. For more information see: <http://www.ethicalmedtech.eu>.
- 
- **Code:** this IMEDA Europe Code of Ethical Business Practice (including the incorporated Questions and Answers) and the Disclosure Guidelines.
- 
- **Disclosure Guidelines:** the Code provisions setting out the public disclosure requirements under the Code.
- 
- **Demonstration Products (Demos):** either single-use or multiple-use products provided free of charge by or on behalf of a Company to HCOs, which are equipped and which have specialists qualified to use them. Demos are provided solely for the purpose of demonstrating safe and effective use and appropriate functionality of a product and are not intended for clinical use. Demos do not include the following:
    - Samples;
    - Evaluation Products;
    - Products provided at no charge as part of a Charitable Donation or as part of a Research or Educational Grant; or
    - Products provided at no additional charge in a supply arrangement, e.g. as part of an agreed discount arrangement, or as substitutes to products pursuant to a warranty.
- 
- **Educational Grants:** provision of funding, Company or third party products or other in kind support to a non-commercial Healthcare Organisation by or on behalf of a 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 Company is interested and/or involved.
- 
- **Employer Notification:** the prior written notification provided to a Healthcare Organisation (e.g. hospital administration) or a Healthcare Professional's superior of any interaction, collaboration or other matter concerning any Company and any Healthcare Professional, the purpose and/or scope of which requires notification under this Code.
- 
- **Entertainment:** Entertainment includes the following activities, but is not limited by them: dancing, live music, sightseeing trips, theatre excursions, sporting events (e.g. skiing, golf or football match) and other leisure arrangements. For the avoidance of doubt background music shall not constitute Entertainment.
- 
- **Evaluation Products:** either single-use or multiple-use products and/or equipment provided free of charge to HCO by or on behalf of a Company for purposes of obtaining evaluative user feedback over a defined period of use when used within the scope of their intended purpose, as per the authorisation in the Russian Federation. Evaluation

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Products do not include the following:

- Demos;
- Samples;
- Products provided at no charge as part of a Charitable Donation or as part of a Research or Educational Grant; or
- Products provided at no additional charge in a supply arrangement, e.g. as part of an agreed discount arrangement, or as substitutes to products pursuant to a warranty.

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

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• **Faculty:** a podium speaker, moderator and/or chair, who presents during an Event in relation to performance of the pedagogic and (or) scientific activity. Poster- presenters are not considered to be Faculty.

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• **Financial Hardship:** extreme and unavoidable financial distress of a Healthcare Organisation resulting from matters outside the Healthcare Organisation's control where the Healthcare Organisation is unable to operate and where patient care is consequently jeopardised. Financial distress resulting in whole or in part from mismanagement of the Healthcare Organisation's funds or other matters within its control is not considered to be financial hardship. Financial Hardship must be documented and objectively substantiated.

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

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• **Guests:** spouses, partners, family, guests of Healthcare Professionals, or any other person who does not have a bona fide professional interest in the information being shared at an Event.

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• **Healthcare Organisation (HCO):** any legal entity (irrespective of its legal or organisational form) that is a healthcare organisation, medical or scientific association or organisation which may have a direct or indirect influence on the prescription, recommendation, purchase, order, supply, utilisation, sale or lease of medical technologies or related services including group purchasing or purchasing for hospital, clinic, laboratory, pharmacy, research institution, foundation, university or other teaching institution, scientific or professional society (except for patient organisations); or through which one or more Healthcare Professionals provide services.

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• **Healthcare Professional (HCP):** any individual (whether clinical or non-clinical specialist, a government official, employee or representative of a government or municipal body or institution, or other public or private sector organization; including but not limited to, physicians, nurses, technicians, laboratory scientists, researchers, research co-ordinators or procurement professionals) that in the course of their professional activities may directly or indirectly purchase, lease, recommend, prescribe, administer, use, supply, procure or determine the purchase or lease of, or who may prescribe medical technologies or related services.

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• **Information Meetings:** any type of Company Event the objective of which is to effect the promotion of a Company's medical technologies and/or related services, including meetings to discuss product features, benefits and use.

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• **Companies:** all actual and associate companies-members (" Companies") of IMEDA Association.

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• **Professional Conference Organiser (PCO):** a legal entity which specialises in the organization and conducting of congresses, conferences, seminars and similar events.

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• **Product and Procedure Training and Education Event:** a type of Company Event that is primarily intended to educate Healthcare Professionals, including by conducting a training form them and/or provision of information on:

- The safe and effective use of medical technologies, therapies and/or related services, and/or
- The safe and effective performance of clinical procedures, and/or
- Related disease areas.

In all cases the information and/or training directly concern a Company's medical technologies, therapies and/or related services.

- 
- **Research Grants:** the provision by or on behalf of a Company of funding, products/equipment and/or in kind services to any non-commercial organisation that conducts research which is made exclusively for supporting the development or furtherance of bona fide, scientifically valid and legitimate research by the recipient the purpose of which is to advance medical, scientific and healthcare knowledge, medical technologies and/or clinical techniques designed to improve patient outcomes.

- 
- **Samples:** single-use or multiple-use products provided free of charge by or on behalf of a Company to HCOs, which are equipped and qualified to use them in order to enable HCPs to familiarise themselves with the products in clinical use. Samples do not include the following:

- Demos;
- Evaluation Products;
- products provided at no charge as part of a Charitable Donation or as part of a Research or Educational Grant; or
- products provided at no additional charge as part of the overall purchase price in a supply arrangement, e.g. as part of an agreed discount arrangement, or as substitutes of products pursuant to a warranty.

- 
- **Scholarships and Fellowships:** Educational Grants provided to a Healthcare Organisation by or on behalf of a Company to support fellowships or scholarships offered by the Healthcare Organisation. Scholarships in this context means an Educational Grant provided to support undergraduates studying in the medical school or medical\biological faculties of non-medical schools whereas a fellowship is a period of intensive training for post-graduate physicians in a chosen clinical sub-specialty (e.g. medical training after a residency). "Scholars" and "Fellows" shall be understood accordingly.

- 
- **Third Party Organised Educational Events:** activities of any type that are planned, budgeted, managed and executed in whole or in part by or on behalf of a person or entity other than a Company to fulfil Healthcare Professional medical educational needs.

- 
- **Third Party Organised Educational Conferences:** a type of Third Party Organised Educational Event that is an independent, educational, scientific, or healthcare policy-making conference organised to promote scientific knowledge, medical advancement and/or the support of effective healthcare and are consistent with relevant guidelines established by professional societies or organisations for such educational meetings. These typically include conferences organised by national, regional, or specialty medical associations/societies, hospitals, Professional Conference Organisers (PCOs), patients organisations or accredited continuing medical education providers.

- 
- **Third Party Organised Procedure Training:** a type of Third Party Organised Educational Event that is primarily intended to provide Healthcare Professionals with information and training on the safe and effective performance of one or more clinical procedures in circumstances where the information and training concern:
    - Specific therapeutic, diagnostic or rehabilitative procedures, namely clinical courses of action, methods or techniques (rather than the use of medical technologies); and
    - Practical demonstrations and/or training for HCPs, where the majority of the training programme is delivered in a clinical environment.
-

For the avoidance of doubt, proctorship and preceptorship are not considered to constitute Third Party Organised Procedure Training.

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- **Transition Period:** the period from 1 January 2020 up to and including 31 December 2020, following which Companies shall fully comply with the requirements of the Code. .
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ANNEX I (added in October 2016, removed references to 2017 in January 2018)

CVS scope: When are CVS assessments required?

		PRIOR CVS APPROVAL			
		IN MEDTECH EUROPE GEOGRAPHIC AREA, INCL. RUSSIA		OUTSIDE MEDTECH EUROPE GEOGRAPHIC AREA	
WHICH TYPE OF SUPPORT CAN COMPANIES PROVIDE TO WHICH THIRD PARTY ORGANISED EDUCATIONAL EVENTS?		<b>NATIONAL</b> (Third Party Organised Educational Events attended by delegates which are local HCPs only)	<b>INTERNATIONAL</b> (Third Party Organised Educational Events attended by delegates coming from at least two countries of the MedTech Europe Geographic Area <sup>1,2</sup> )	<b>INTERNATIONAL</b> (Third Party Organised Educational Events attended by delegates who are Healthcare Professionals registered and practising in the MedTech Europe Geographic Area <sup>3</sup> )	<b>INTERNATIONAL</b> (Third Party Organised Educational Events to which no Healthcare Professionals registered and practicing in the MedTech Europe Geographic Area attend, neither as speakers or delegates)
EDUCATIONAL GRANTS <sup>4</sup> PROVIDED TO SUPPORT A THIRD PARTY ORGANISED CONFERENCE	Educational Grant to support the general running of a conference	Allowed <sup>5</sup> .	Subject to CVS decision	Allowed. Not subject to CVS decision	Out of scope of the application of the Code <sup>6</sup>
	Educational Grants that includes funds to support HCP attendance to the conference	Allowed.	Subject to CVS decision	Subject to CVS decision	N/A
	Educational Grants that includes funds to support third party Faculty	Allowed.	Subject to CVS decision	Allowed. Not subject to CVS decision	N/A
COMMERCIAL ACTIVITIES	Service agreement for speakers in satellite symposia	Allowed.	Subject to CVS decision	Allowed. Not subject to CVS decision	N/A
	Booths/advertising	Allowed.	Subject to CVS decision	Allowed. Not subject to CVS decision	Out of scope of the application of the Code
DIRECT SPONSORSHIP OF HCPs REGISTERED AND PRACTISING IN THE MEDTECH EUROPE GEOGRAPHIC AREA	Direct sponsorship of HCPs as delegates (passive participation)	Not allowed.	Not allowed.	Not allowed.	N/A
	Direct sponsorship of HCPs as Faculty (active participation)	Not allowed.	Not allowed.	Not allowed.	N/A

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

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

<sup>3</sup> For avoidance of doubt, this category of "Third Party Organised Educational Events attended by delegates who are Healthcare Professionals registered and practicing in the MedTech Europe Geo- graphic Area" has to be understood as covering only Healthcare Professionals from the MedTech Europe Geographic Area benefiting from an Educational Grant.

<sup>4</sup> . Educational Grants: means provision of funding, Company or third party products or other in kind support to a Healthcare Organisation by or on behalf of a 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 Company is interested and/or involved.

<sup>5</sup> Allowed means no CVS decision is required but the provisions of the IMEDA Europe Code of Ethical Business Practice and laws and regulations applicable on the territory of the Russian Federation still apply.

<sup>6</sup> Out of scope: Means the Code does not apply given that the situation does neither involve a Company interacting with an HCP or HCO registered and practicing in the MedTech Europe Geographic Area nor does the activity take place in the MedTech Europe Geographic Area.





## ANNEX II (added in October 2016)

### Disclosure Guidelines Template Example\*

TEMPLATE								
Full HCO Name	HCOs: city where registered	HCOs: Country where registered	HCO Registered Address	Unique country local identifier	A. Educational Grants to Support Third Party Organised Events/orto Support HCP Participation at Third Party Organised Educational Events	Object (Optional)	B. Other Educational Grants to HCOs (including Scholarships, Fellowships and Grants for Public Awareness Campaigns).	Object (Optional)
HCO/PCO1					Yearly amount	Optional	Yearly amount	Optional
HCO/PCO2					Yearly amount	Optional	Yearly amount	Optional
etc.					Yearly amount	Optional	Yearly amount	Optional

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

**A:** It is a unique and sustainable reference to identify Healthcare Organisations. Disclosing Companies will use the Healthcare Organisation's taxpayer identity number ( INN) as unique country local identifier of the Russia-registered HCO by default. If the HCO is registered outside of Russia and does not have the taxpayer identifier, other identifier which is unique and uniform for all disclosing Companies, may be used as a unique country local identifier.

ANNEX III (added in November 2016)

The MedTech Europe Geographical Area



The MedTech Europe Geographic Area currently includes European Economic Area (EEA) zone countries, as well as countries where MedTech Europe Associations, including IMEDA, are located.

The up-to-date list of such countries is published in the last version of the MedTech Europe Code accessible on <https://www.ethicalmedtech.eu/resources/>

## ANNEX IV

### Verification Of The Use Of Funds

How can a Company verify that the Educational Grant is in fact used for the intended purpose as agreed in the Educational Grant agreement?

A Company should set up an internal verification process for the purpose of ensuring that the funds provided through an Educational Grant are used for the agreed intended purpose. For example, such a process could include verification of every single Grant provided by a Company or periodic verification of a selected sample of Grants, after the Event takes place or before any subsequent request for an Educational Grant. This procedure must be conducted in strict compliance with the applicable personal data legislation.

Examples of the documents requested by Company for verification purposes could include, but are not limited to, the following:

Grant to support Healthcare Professionals' attendance at the Third Party Organised Educational Event:

- Attendance proof (e.g. hotel check out form, signed attendance list, a certificate issued by the Event organiser etc.)
- Travel proof (e.g. flight/train tickets)
- Copy of the receipts of taxi fares, meals, etc.
- Where allowed, pictures of the Event.

Grant to support the costs related to organisation of the Third Party Organised Educational Event:

- Budget breakdown listing the general expenses of the Event
- Accounting records, copies of invoices, receipts
- Verifications performed by company staff on-site during the Event
- Written confirmation from the Event Organiser that the funds were spent as intended
- Documentation of the speaker's presentation (e.g. presentation slides)

Grant provided in a form of a Scholarship or Fellowship:

- Activity records of the educational programme
- Certification of enrolment from the institution or professor in charge
- Progress report prepared by the ultimate recipient of the Grant funds

If a Grant recipient fails to provide the requesting Company with the documents or if a Company determines that the Grant funds were not used as provided in the Grant agreement, the Company should take this into account when assessing any future funding request from the same Healthcare Organisation.

## ANNEX V

# Methodology Note Example

### Structure

- Introduction
- Executive summary of the methodologies used for disclosure purposes
- Definitions
  - Recipients
  - Types of Educational Grants
- Disclosure scope and timelines
- Disclosures in case of partial use or cancellation of the Grant
- Cross-border activities (if applicable)
- Specific considerations:
  - Agreements with effective term exceeding one year
    -
- Disclosure Form
  - Date of submission
  - Currency in case of payments made in different currencies
  - VAT included or excluded and any other tax aspects
- Disclosure financial data and amount of Educational Grants provided
- Calculation rules

**Disclaimer:** This Methodology note is provided as a template to support Companies in the implementation of these Disclosure Guidelines. Any other template may be equally valid provided they comply with the general requirements set out in *Chapter 2 point 4 of the Disclosure Guidelines Methodology*.

## ANNEX VI

### Direct support to HCP participation in Events as of 1 January 2018

		Direct Support for HCP attendance(*)	
Event	Setting	Faculties	Delegates
Third Party Organised Educational Conference	Main Event / Independent Scientific Program	Not allowed	Not allowed
	Satellite Symposium	Allowed (through a service arrangement)	Not allowed
	Exhibition booth	Allowed (if the activity complies with the satellite symposia requirements)	Not allowed
Third Party Organised Procedure Training meeting* <small>*Criteria to distinguish a Third Party Organised Procedure Training meeting can be found in Q&amp;A 16</small>		Allowed (through a service arrangement)	Allowed (if participation is necessary for the provision of genuine services through a service arrangement)
Company Events	Product and Procedure Training and Education Event	NOT taking place around or at the same time as a Third Party Organised Educational Event	Allowed (through a service arrangement)
		Taking place around or at the same time as a Third Party Organised Educational Event	Allowed (through a service arrangement)
	Business Meeting	NOT taking place around or at the same time as a Third Party Organised Educational Event	Not allowed
		Taking place around or at the same time as a Third Party Organised Educational Event	Not allowed

#### Description

**Delegate:** "Delegate" is any Healthcare Professional who is attending passively a Company Event or a TPOE and cannot be considered as "Faculty". For avoidance of doubt, poster-presenters are considered to be Delegates from the perspective of their participation in the Event.

**Satellite Symposium:** Common elements of Satellite Symposia are:

- It takes place at a Third Party Organised Event (TPOE) and it is part of the TPOE official program (i.e. not focused on marketing specific products);
- The Company is responsible for the content subject and its review by the Organiser where required;
- It's open to any delegate, not only to selected individuals;
- It has Company branding and the Company can promote the Satellite Symposia to clients.

**Faculty:** "Faculty" in this chart is someone who is considered as speaker, for example someone who gives a presentation whether in a Company Event or a TPOE; is moderating/chairing a session and therefore needs to prepare ahead of the presentation/moderation.

#### Guidance

**Faculty:** In order to determine whether an event is a TPOE or a Company Event, the following aspects should be taken into account:

- Open events (not only Company's customers) are typical of TPOE, and in this case, it is a Third-Party chooses HCPs attending;
- Who is primary initiator of the Event: how much is the Third-Party vs. the Company involved, who is driving the agenda?
- CME accreditation is an TPOE indication;
- TPOE are generally dedicated to more than one or few products;
- Single-sponsored events are often Company Events.

## ANNEX VII

# The Criteria Applicable to Third Party Organised Procedure Trainings

Chapter 2 of the [IMEDA Code of Ethical Business Practice](#) provides that Companies may support Third Party Organised Procedure Trainings by provision of Educational Grants (in accordance with Chapter 4: Charitable Donations and Grants).

Third Party Organised Procedure Training means a type of Third Party Organised Educational Event that is primarily intended to provide Healthcare Professionals with information and training on the safe and effective performance of one or more clinical procedures where such information and training concern:

- Specific therapeutic, diagnostic or rehabilitative procedures, namely clinical courses of action, methods or techniques (rather than the use of medical technologies); and
- Practical demonstrations and/or training for HCPs, where the majority of the training programme is delivered in a clinical environment.

For the avoidance of doubt, proctorship and preceptorship are not considered to constitute Third Party Organised Procedure Training.

This exception is to be narrowly interpreted.

Cross-border and international Third Party Organised Educational Conferences need to be submitted to the Conference Vetting System (CVS).

For avoidance of doubt, Proctorships and Preceptorships taking place on HCO premises are not considered to be either a Third Party Organised Educational Event or a Third Party Organised Procedural Training.

### Criteria for Third-Party Organised Procedure Trainings

**Programme:** Unlike Third-Party Organised Educational Conferences which are theoretical in nature, practical, hands-on activities comprise the majority of the programme of Third-Party Organised Procedure Trainings (“TPPTs”).

TPPTs are often referred to as “courses”, rather than conferences or seminars. Examples may include courses aimed at acquiring or improving the Healthcare Professional’s skills in minimally invasive surgery; orthopaedic trauma surgery; or the implantation of cardiac rhythm devices; etc.

The programme must be focused on acquiring specific medical skills relevant to certain medical procedures as opposed to products, or medical technologies.

The programme must include practical sessions. In order to be considered a TPPT, the practical sessions must in all cases represent more than 50 % of the full programme with hands-on sessions representing at least two-thirds of the practical sessions. This requirement must be clearly indicated in the programme of the TPPT.

Will be considered practical sessions:

- **Hands-on sessions** in which all attendees to the TPPT participate actively.

In these sessions attendees perform specific procedures on settings and environments appropriate for the practice of the relevant procedure. Examples of hands-on may include surgery simulations where the technologies relevant to the specialty are practiced on cadavers; skin models; synthetic bones; cath labs; etc.

To ensure that attendants are able to benefit from the active aspects of hands-on sessions to the maximum extent, no “station” (model, cadaver, table, etc.) can in principle have more than four participants.

For ethical considerations, when human cadavers are used, up to eight participants may share a “station”.

- **Streaming (e.g. video, 3D-rendering software, augmented reality) or demonstrations of live surgeries** followed immediately by participation of attendees in related hands-on sessions.

The sessions would only qualify as practical sessions if they are followed by hands-on sessions because they do not normally require active participation of the attendees.

Where the practical session portion of the TPPT consists entirely of participants merely watching a live surgery or a streaming of a surgery, this is not sufficient to qualify as a TPPT due to lack of active participation and hands on sessions.

- **Case study sessions** when the trainees learn about the procedure preparation, best practices and progressive methods, as well as all complications handling of the procedure(s) from specialty expert(s). Those sessions must be interactive and based on pictures, videos, animations, 3D rendering software, augmented reality, etc.

**Venue:** The hands-on sessions of TPPTs are typically organised in either a clinical environment or in places suitable for or set up to simulate medical procedures.

Examples of a clinical environment include hospitals or clinics, where medical treatment on real patients may be given (Operating Room, Cath. Lab).

Examples of simulation settings include conference or meeting rooms which are appropriately equipped with relevant simulation devices/systems or experimental laboratories suitable for training on cadavers, skin models, synthetic bones, live animals in accordance to applicable regulations and ethical rules, etc.

**Stand-alone event:** Third-Party Organised Procedure Trainings must be stand-alone. Where the majority of the Training is not given in a clinical environment, for example, where the Training is organised in connection, adjacent to or at the same time as a larger Third-Party Organised Educational Conference, that Training will not qualify as a Third-Party Organised Procedure Training as defined in the Code.

**Size:** Given the essential practical element of a Third-Party Organised Procedure Training, and given that the importance of the fact that Companies would know the identity of the HCPs participating in the course, the quantitative representation of participants of such trainings is usually relatively small.

However, provided that the above criteria are met, the quantitative representation of participants may not be a determining factor.