

**Questions and Answers (Q&A) Relating to the International Medical Device
Manufacturers Association (IMEDA) Code of Ethical Conduct for Interactions with
Healthcare Professionals**

Clause 2 (Contractual Arrangements)

Q1: "Contractual arrangements with Healthcare Professionals should include guarantees and assurances of Healthcare Professional that provided to the Company services are not in direct or indirect conflict of interest between his employment / job duties at the main place of work and such services provided by a Healthcare Professional to the Company, as well as provisions on responsibilities of Healthcare Professional to disclose the information about arrangements with the Company to the Healthcare Professional's institution or his another employer in the manner prescribed by the rules of his institution and / or by applicable law...".

The law does not obligate an HCP to disclose information about research and/or educational contracts executed by the HCP with companies. Isn't this requirement of the Code excessive?

A1: This provision requires that a contract include a clause obligating an HCP to disclose information about the contractual arrangement to the institution that employs the HCP or to another employer in the manner prescribed by the regulations of the institution and/or applicable laws. We therefore believe that if the relevant disclosure procedure is not provided by the regulations of the relevant institution or applicable laws during the effective term of the contractual arrangement, failure by the HCP to disclose information about the contractual arrangement to the institution that employs the HCP will not constitute a formal violation of this provision of the Code.

At the same time, it should be noted that disclosure of such information by the HCP practically eliminates situations where an HCP could be accused—in the absence of clearly formulated requirements with respect to scientific and pedagogical activity of the HCP—of unduly receiving and concealing income from companies or violating the requirements of Article 75 of the Federal law “On the Fundamentals of Health Protection of the Citizens in the Russian Federation” that obligates the HCP to inform management about a potential conflict of interest.

Q2: "... If applicable laws, regulations or institutional rules specifically require disclosure to a different body, in this case disclosure should be made in accordance with the applicable laws, regulations or rules".

In what cases should a contractual arrangement for services between an HCP and a company be approved by an external oversight agency? Which agency possesses this authority?

A2: The acting legislation does not currently provide for cases in which a contractual arrangement like this would have to be approved by an external agency and does not specify the agency that possesses or will possess the relevant authority. At the same time, general oversight of compliance by HCPs with the applicable laws governing the fundamentals of public healthcare in the Russian Federation currently belongs to the competence of agencies of the Federal Service of Surveillance in Healthcare (Roszdravnadzor).

Q3: What is the meaning of "extravagant travel arrangements", "lavish meals", and "reasonable expenses"?

A3: The meaning of the terms "extravagant travel arrangements", "lavish meals", and "reasonable expenses" is defined by the economic rationale of such expenses and the nature of services provided under the contract (for instance, business class tickets may be justified for long-distance flights, while business class tickets for short flights may constitute an extravagant travel arrangement), and also according to internal regulations and limits established for these kinds of expenses at a certain company (for instance, corporate regulations may allow buying sleeping car tickets or only compartment car tickets; business class tickets for flights shorter than 8 hours, etc.).

Clause 3 (Third Party Educational Programs)

Q4: "Such grants should be made only following a written request from the conference organizer...". Can a request sent via email be considered a written request?

A4: If the request has arrived from the official email address of the event organizer and signed by an authorized representative on behalf of the organizer, this request can be considered a written request. At the same time, we recommend following up with hardcopy requests on any requests sent via email.

Q5: " Companies cannot directly or through third parties provide any contrary to current legislation support to specific Healthcare Professionals for participation in such conferences, as well as cannot cover their travel, accommodation and other expenses" – Does this mean that it is impossible to arrange for a HCP to attend the Congress?

A5: What is meant in this case is that companies cannot cover the expenses of HCPs for participation in the conference directly or through third parties (which include travel agencies, distributors, etc.). However, the conference organizers themselves may direct a portion of funds received from companies toward covering reasonable expenses for organizing the participation of HCPs in such conferences (including economically reasonable travel expenses of HCPs traveling along a straight route to the event venue and back, reasonable meal and accommodation costs). At the same time, event organizers may enlist third parties to this end, who may act on behalf of the event organizers. Companies may also provide educational grants to nonprofit organizations, which may be used by such nonprofit organizations, among other things, to cover reasonable expenses for organizing the participation of HCPs in third-party educational programs.

Q6: A conference organizer has asked a company to transfer payment to a third company. Is this acceptable?

A6: We believe that organizing an event belongs to the exclusive competence of the event organizer and that this organizer should cover all organizational costs using its own funds, including funds received as part of educational grants provided by companies. Transfers by companies of funds intended as an educational grant for the event organizer to any third parties at the request of the event organizer, provided that they are justified and properly documented (including a contractual arrangement between the event organizer and such third party whose subject matter is consistent with the goals for which the relevant grant has been provided, and also existence of current monetary obligations of the organizer to such third party under this contractual arrangement, a payment instruction duly issued by the organizer for the company to transfer a portion of funds payable by the company to the organizer as a grant to the relevant third party as payment of the organizer's obligations to such third party under such contractual obligations) remain at the discretion of the company, but is highly undesirable because in certain circumstances oversight agencies may not recognize such payments as grants. Moreover, such mutual settlements are bound to create tax assessment complications.

It also stands to mention that Russian law allows only nonprofit organizations to execute a donation (grant) agreement.

Q7: What is the recommended way to arrange meals and refreshment beverages for event participants?

A7: The recommended form of meals is an open or standing buffet.

Q8: How can companies keep track of spending to verify that conference organizers do not spend funds on undue rewards for HCPs?

A8: For a proper accounting of expenses, the relevant contracts should obligate organizers to submit an expense report along with photocopies of documents proving that grant funds have been used for the purposes intended (the contract with the organization / institution on whose premises the conference was arranged and a photocopy of the payment order; cash receipts, etc.).

Clause 4 (Company-Organized Education and Training)

Q9: Is it always prohibited to hold events in resort hotels and at other recreational venues?

A9: Events may be held in hotels located in a resort area if this choice of venue is warranted by its proximity to the permanent address of work or residence of the majority event participants, or if the company's overall expenses for holding this event in such a hotel will be much lower than expenses for holding the event at any other venue, provided that the hotel specialization is

business-oriented (which includes the availability of the required number of conference halls with enough seats and also accompanying equipment for conferences and other research and educational events, etc.) and not recreational (health rehabilitation) or exclusively designed for resort stay. At the same time, organization of HCP participation in such an event must not involve providing recreational, health rehabilitation, and/or entertainment services to healthcare professionals.

If there are sufficient grounds and reasons for holding events at such venues, the company must prepare an appropriate justification prior to choosing such venues.

Q10: " Companies cannot provide contrary to current legislation financial support to individual Healthcare Professionals for participation in such Training and Education programs, including cover their travel, accommodation and other expenses."

In other words, financial support is allowed as long as it does not contrary to the law, for example by executing a contract with a healthcare institution. What other forms of financial support are also possible in this case?

A10: Payment of funds to an HCP outside contractual arrangements indicated in Clause 2 of the Code is prohibited by law and inadmissible.

In the presence of direct prohibition for HCPs to receive gifts from Companies, when the Company directly or through its representative covers expenses for participation by individual HCPs in educational events outside contractual arrangements indicated in Clause 2 of the Code may constitute a gift in certain circumstances and, therefore, a violation.

Meanwhile, when the company executes a contract with a healthcare institution as described in Paragraph 3, Clause 4 of the Code, this does not constitute providing financial support to an individual HCP and does not contravene applicable laws. Nonetheless, this example is not a limit. Legal practice may identify other forms of financial support for an HCP's participation in an educational event (without payment of funds to the HCP), which do not constitute a gift and, therefore, do not contravene applicable laws.

We believe that, given the direct prohibition for an HCP to receive funds or gifts from companies, applicable laws do not currently make it possible for companies to provide direct financial support, including payment of funds, to individual HCPs for purposes of their participation in educational events when such support is provided outside the framework of contractual arrangements indicated in Clause 2 of the Code. Meanwhile, when the company executes a contract with a healthcare institution as described in Paragraph 3, Clause 4 of the Code, this does not constitute providing financial support to an individual HCP and does not contravene applicable laws.

Q11: Don't the provisions of Clause 4 of the Code restricts the ability of HCPs to participate in training and acquisition of new knowledge of vital importance, which is an integral part of the general process by which the HCP is providing educational services under contracts for educational services executed with this HCP? In other words, HCPs need first to acquire knowledge on how to use innovative products and then convey this knowledge to other HCPs, which is why participation of HCPs in the relevant trainings is interconnected and constitutes an integral part of the process of providing educational services.

A11: Participation by HCPs in training and acquisition of new knowledge, including by participating in educational activities, if this is provided for and expressly stipulated in the contract for educational services executed with the HCP and is an integral part of the process of providing educational services under such contract, does not fall under Clause 4 of the Code and is governed by the provisions of Clause 2 "Contractual Arrangements".

Clause 5 (Sales and Promotional Meetings)

Q12: Clause 5 of the Code does not contain provisions similar to those in Clause 4 to the effect that companies may not provide financial support in contravention of the law to individual HCPs for purposes of their participation in product and service sales and promotional meetings. We believe, however, that this clause should include the same restrictions. Could you clarify this aspect?

A12: Absolutely. In light of the fact that HCPs are subject to general restrictions when it comes to receiving gifts and funds from companies and their representatives, the provisions of Clause 4 of the Code to the effect that companies may not provide financial support to individual HCPs in contravention of applicable laws also apply to product and service sales and promotional meetings indicated in Clause 5 of the Code.

Clause 7 (No Gifts or Entertainment)

Q13: Are souvenirs considered to be gifts?

A13: Yes, they are. Everything that has a material value is considered to be a gift.

Q14: Are pens and notepads, memory flash-drive sticks with the company's logo included in the package of Congress documents considered to be gifts?

A14: If the notepad and pen are not expensive and are distributed as stationery for making writing down information at the conference, they are not considered to be gifts. At the same time, if a pen is an expensive item and constitutes a certain value, transfer of this pen can be interpreted as a concealed gift by the company to the HCP.

As for memory flash-drive sticks, if they are not expensive either and if they store exclusively materials pertaining to the event, this memory stick can be considered an integral part of the event materials. At the same time, it is preferable for the memory size of this memory flash-drive stick to be roughly equivalent to the size of event materials stored on it. An empty memory stick, even one that is relatively cheap, or an expensive memory stick with a large memory size (that significantly exceeds the memory needed to store the event materials) can be considered a gift.

Q15: Is it allowed to give away pens and memory flash-drive sticks at the exhibition booth (part of the congress), as long as they are given away to everybody?

A15: We believe that inexpensive pens bearing the company logo or other advertising can be used as advertising materials and distributed together with other advertising. At the same time, to rule out the risk of potential ambiguous interpretation, we recommend not giving such pens away to participants, but placing them visibly in the booth so event participants could approach the booth and take such pens on their own if they wish to do so. As for memory flash-drive sticks, if they are inexpensive, distributed as advertising materials, and store exclusively the relevant advertising information about the company and, if possible, are write-protected to prevent such information from being overwritten with other data, such memory sticks can be considered advertising material. At the same time, an empty memory stick, even one that is relatively cheap, or an expensive memory stick with a large memory size (that significantly exceeds the memory needed to store the event materials) and is not write-protected to prevent such information from being overwritten with other data, can be considered as a gift.

Q16: If a company representative has known an HCP for a long time, is he or she allowed to make a personal gift to the HCP not in the capacity as an employee of the Company?

A16: Applicable laws do not restrict gift-giving by individuals to HCPs, except in the cases where gifts are made by individuals who are patients of such HCPs (or relatives of such patients) and/or representatives of the relevant companies, and with respect to HCPs who are public or municipal servants – also gifts associated with their official position or performance of their official duties. However, given the fact that it is fairly difficult to establish clearly that at the time of presenting the gift to an HCP the company employee was not acting as a company representative but as a private individual, there is a high probability that the fact of the HCP receiving such a gift could be interpreted as a violation of the prohibition to receive gifts from companies and their representatives, especially so when the HCP during his duty has interacted in any way with such a company employee or if the HCP's work is directly associated with specific medical devices manufactured by the company that employs this employee.

Clause 9 (Demonstration and Evaluation Products)

Q17: "Companies can provide Medical Technologies to nonprofit medical institutions free of charge for demonstration and evaluation purposes..."

What is meant by "nonprofit medical institutions"? Can samples (evaluation products) be provided to private clinics?

A17: A nonprofit healthcare institution is any healthcare institution falling under the definition of a nonprofit organization. Considering that gifts between commercial organizations are prohibited under civil law, free transfer of samples or other products from a commercial organization to a commercial healthcare institution, including to private clinics, may be interpreted as a violation of this prohibition.