

UST-42 version 1 Sponsoring and Provision of Gifts and Other Benefits to Experts and Employees of Healthcare Providers in Advertising for Medical Devices and in Vitro Diagnostic Medical Devices

This Guideline supersedes Guideline UST-42 as of 31 October 2023.

The Guideline is based upon legislative conditions stipulated by:

- Act No 40/1995 Coll., on Advertising Regulation and on Amendments to Act No 468/1991 Coll., on the Operation of Radio and Television Broadcasting, as amended (hereinafter referred to as “Act No 40/1995 Coll., on Advertising Regulation”)

This Guideline applies only to advertising for medical devices (hereinafter referred to as “MD(s)”) and in vitro diagnostic medical devices (hereinafter referred to as “IVD(s)”) and provides greater detail to the information presented in Guideline UST-39 Regulation of Advertising for Medical Devices and in Vitro Diagnostic Medical Devices concerning the sponsoring and provision of gifts and other benefits to experts and employees of healthcare providers in advertising for MDs and IVDs referred to under Act No 40/1995 Coll., on Advertising Regulation, falling within the powers of the State Institute for Drug Control (hereinafter referred to as the “Institute”). The Guideline is of recommendatory nature.

This Guideline applies to the provision of gifts or other benefits and to sponsoring targeted at persons authorised to prescribe and dispense MDs and IVDs and at employees of healthcare providers. The purpose of the legislative conditions is, inter alia, that experts and employees of healthcare service providers perform their tasks objectively without being influenced by direct or indirect financial incentives in the prescribing, dispensing, use, and ordering of MDs and IVDs.

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Sponsoring

Pursuant to the provision of Section 1(4) of Act No 40/1995 Coll., on Advertising Regulation, sponsoring “*shall mean a contribution provided in order to support the manufacturing or sale of goods, provision of services or other performance of the sponsor. A sponsor shall mean a legal or natural person providing such contribution for this purpose.*”

Furthermore, pursuant to the provision of Section 5k(1) of Act No 40/1995 Coll., on Advertising Regulation, the definition of the term advertising is being extended above the scope of the provision of Section 1(2) of Act No 40/1995 Coll., on Advertising Regulation in the area of MDs and IVDs, as advertising for MDs and IVDs “*shall be deemed to be also any forms of information provision, surveys or incentives carried out in order to support the prescribing, dispensing, sale or use of medical devices and in vitro diagnostic medical devices. These concern, in particular:*

- a) visits of sales representatives with medical devices and in vitro diagnostic medical devices to persons authorised to prescribe or dispense them;*
- b) provision of samples of medical devices and in vitro diagnostic medical devices;*
- c) support of prescription, dispensing or sale of medical devices and in vitro diagnostic medical devices by means of gifts, consumer competitions and an offer or promise of any benefit or financial or material remuneration;*
- d) sponsoring of meetings held in order to support prescription, sale, dispensing or use of medical devices and in vitro diagnostic medical devices and visited by experts; or*
- e) sponsoring of scientific congresses and other similar meetings attended by experts and reimbursement of the costs of travel and accommodation associated with their attendance.”*

As the provision of a sponsor contribution can be considered to be an incentive, the aim of which is to support the manufacture or sale of goods, provision of services or other performance of the sponsor, the provision of Section 5k(1) along with other provisions of Act No 40/1995 Coll., on Advertising Regulation, governing advertising for MDs and IVDs will apply also to sponsoring in this area.

A meeting attended by experts and employees of healthcare providers becomes advertising if its purpose is support of prescribing, sale, dispensing, consumption or ordering of MDs and IVDs. For such meeting to be subjected to regulation by law, an advertising activity must be carried out as part of the meeting.

A sponsor hence may sponsor a scientific congress, a meeting of experts or an expert's attendance at such events. Methods of sponsoring as per law may vary, nevertheless, sponsoring is subjected to the conditions set forth by law. In association with sponsoring, it is necessary to distinguish scientific congresses from meetings of experts and employees of healthcare providers held primarily for the purposes of supporting prescribing, sale, dispensing, consumption or ordering of MDs and IVDs. The difference is as follows: the aim of a scientific congress is, in particular, the provision of expert information, expert education and sharing of experience among experts or employees of healthcare providers, without pursuing the goal of support to prescription, deliveries, sale, dispensing, consumption or ordering of MDs and IVDs, and hence is not, as such, deemed to be advertising within the meaning of the law. Nevertheless, this does not pre-empt the support of sale and consumption, orders of MDs and IVDs in the form of exhibition stalls and corporate symposia of MD and IVD companies in the course of the scientific congress; such advertising activity shall then be assessed separately.

Provision of catering and accommodation within the scope of the sponsored events

Sponsoring of promotional meetings (held for the purposes of supporting prescribing, deliveries, sale, dispensing, consumption or ordering of MDs and IVDs) attended by experts or employees of healthcare providers is advertising for MDs and IVDs. At such meetings, an expert or employee of healthcare provider may be provided only with reasonable catering and accommodation. The scope of catering and accommodation provided free of charge during a promotional meeting must be reasonable and must not be extended to persons other than the experts and employees of healthcare providers, i.e., it shall not apply, for instance, to the family members of the experts and of employees of healthcare providers. The condition for catering, accommodation, and travel expenses provided in this manner is that it must be limited to the primary purpose of the meeting (provision of promotional information) and that it must be adequate, i.e., provided within the predefined premises and time of the meeting at a necessary extent.

Sponsoring of scientific congresses

Sponsoring of scientific congresses and reimbursements of the costs of travel and accommodation is deemed to be advertising for MDs and IVDs. The amount of the sponsor contribution provided to the congress organiser is not limited by law. As part of reimbursement of costs associated with the scientific congress, it is possible to reimburse to the expert, congress attendee the necessary costs associated with his/her attendance – the enrolment fee, travel expenses, accommodation, and catering.

The condition for the provided accommodation and catering is that it must be limited to the primary purpose of the scientific congress and that it must be reasonable, i.e., provided within the predefined premises and time of the meeting in a necessary scope. The provided catering must not upstage the primary purpose of the scientific congress, the exchange of expert information.

Sponsoring the participation of experts and employees of healthcare providers in virtual scientific congresses, i.e., those that are conducted via remote access and replace or complement face-to-face expert events attended by experts and employees of healthcare providers may assume only the form of reimbursement of the enrolment fee, access to the expert platform. Sponsoring of virtual scientific congresses attended by experts and employees of healthcare providers may also assume the form of a sponsor contribution for the organiser or host of such event.

In sponsoring a meeting attended by experts and employees of healthcare providers as well as a scientific congress, a sponsor will get in conflict with the provision of Section 5m(3) of Act No 40/1995 Coll., on Advertising Regulation if in their sponsor contribution they reimburse for the expert or employee of a healthcare provider unreasonable costs of travel, catering, accommodation, stay and travel of another

person who is not an expert or employee of a healthcare provider or by providing the expert or employee of a healthcare provider with a gift or other benefits (material gifts, optional trips, visits to concerts or theatres, etc.). It is possible to provide only such gifts or benefits that are associated with the activities conducted by the expert or employees of healthcare providers and that are of insignificant value (see “Provision of gifts and other benefits to experts” below).

Provision of gifts and other benefits to experts

The provision of Section 5k(1)(c) of Act No 40/1995 Coll., on Advertising Regulation, deems also the support of prescribing, dispensing, and sale of MDs and IVDs by means of gifts, consumer competitions and offers or promises of any benefit or financial or material remuneration to be also advertising for MDs and IVDs.

The provision of Section 5m(2) of Act No 40/1995 Coll., on Advertising Regulation significantly restricts this type of advertising targeted at experts and employees of healthcare providers, as, with some exceptions, it forbids offers, promises or provision of gifts or other benefits. In association with advertising for MDs and IVDs *“targeted at experts and employees of healthcare providers, it is forbidden to offer, promise or provide them with gifts or other benefits unless these are of insignificant value and are related to the expert activities carried out thereby.”* Both conditions must be met at the same time. As the term “insignificant value” does not represent a specific value, the Institute deems insignificant value to be such gift or other benefit provided by one entity to one expert which does not exceed the total amount of 1,500,- CZK per one calendar year.

In addition to the provisions limiting the donor in the provision of gifts and other benefits to experts and employees of healthcare providers, the law also limits the recipient of the gift or other benefit by the provision of Section 5m(4) of Act No 40/1995 Coll., on Advertising Regulation, which stipulates that in association with advertising for MDs and IVDs, experts and employees of healthcare providers must not request or accept benefits forbidden by law.

Penalties for offences

The law lays down financial penalties for breaches of the aforementioned provisions.

For breach of the provision of Section 5m(2) of Act No 40/1995 Coll., on Advertising Regulation, constituting an offer, promise or provision of gifts or other benefits to an expert or employee of a healthcare provider contrary to Section 5m(2) of Act No 40/1995 Coll., on Advertising Regulation, the donor may be penalised with a fine in an amount of up to 2,000,000,- CZK.

For breach of the provision of Section 5(3) of Act No 40/1995 Coll., on Advertising Regulation, constituting cases of provision of unreasonable free catering and accommodation, a fine in an amount of up to 1,000,000,- CZK may be imposed.

An expert or employee of a healthcare provider will commit an offence/administrative offence by requiring or accepting benefits forbidden by Section 5m(2) of Act No 40/1995 Coll., on Advertising Regulation or those that are contrary to Section 5m(3) of Act No 40/1995 Coll., on Advertising Regulation. An expert or employee of a healthcare provider may be penalised by a fine in an amount of up to 100,000 CZK for accepting or requesting gifts or benefits of greater than insignificant value that are not related to the activities performed by the expert or employee of a healthcare provider, or for accepting unreasonable catering and accommodation at a promotional meeting attended by experts and employees of healthcare providers or at a scientific congress.