

Information for Experts and Employees of Healthcare Providers Concerning Advertising for Medical Devices and in Vitro Diagnostic Medical Devices

The State Institute for Drug Control hereby provides experts and employees of healthcare providers with answers to questions in order to familiarise them with requirements governing the advertising for medical devices (hereinafter referred to as “MDs”) and in vitro diagnostic medical devices (hereinafter referred to as “IVDs”) in compliance with 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. More details on the topic of advertising for MDs and IVDs is publicly available from <https://www.niszp.cz/cs/dozor-nad-reklamou>.

In general, advertising is understood to be an announcement, demonstration or other presentation disseminated particularly via communication media with the objective to support business, namely to support consumption or sale of goods, construction, lease or sale of real estate, sale or utilisation of rights or liabilities, support for service provision, and trademark promotion.

Advertising for MDs and IVDs is considered to be also any forms of provision of information, surveys or incentives carried out in order to support prescription, dispensing, sale or use of MDs and IVDs. This concerns, in particular:

- visits of sales representatives with MDs and IVDs to persons authorised to prescribe or dispense them;
- provision of specimen MDs and IVDs;
- support of prescription, dispensing or sale of MDs and IVDs by means of gifts, consumer competitions and an offer or promise of any benefit or financial or material remuneration;
- sponsoring of meetings held in order to support prescription, sale, dispensing or use of MDs and IVDs and visited by experts; or
- sponsoring of scientific congresses and other similar meetings attended by experts and reimbursement of the costs of travel and accommodation associated with their attendance.

*What are the **necessary requirements governing advertising for MDs and IVDs** targeted at experts and employees of healthcare providers?*

✓ Advertising for MDs and IVDs targeted at experts and employees of healthcare providers may be disseminated **solely via communication media intended primarily for these persons**, namely in specialised publications, specialised printed publications, specialised audiovisual works or in the form of direct communication with these persons, and it **must contain**:

- sufficient, evidence-based and objective data that allow to make one’s own opinion of the clinical benefit, safety, and performance of the specific MD and IVD; data taken over from specialised publications or from specialised printed publications must be accurately reproduced and their source cited.

✓ The subject of the advertising may only be a medical device, which may be marketed in compliance with effective legislation governing MDs and IVDs.

*Is it possible to **provide specimen MDs and IVDs** to experts and employees of healthcare providers in association with advertising for MDs and IVDs?*

Yes, it is, in quantities necessary to try the MDs and IVDs out and in accordance with the intended purpose of the device. A specimen MD and IVD provided in this manner must be visibly labelled with the words “**Sample not for sale**” or “**Free sample**”.

*What are the **conditions governing the sponsoring of advertising for MDs and IVDs** targeted at experts and employees of healthcare providers?*

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Generally, sponsoring is understood to be a contribution provided in order to support the manufacture or sale of goods, provision of services or other procedures of the sponsor. A sponsor means a legal or natural person who provides such contribution for this purpose.

When sponsoring meetings held in order to support the prescription, sale, dispensing or use of MDs and IVDs and visited by experts, or sponsoring scientific congresses and other similar meetings attended by experts and reimbursement of the cost of travel and accommodation associated with their attendance, the catering, accommodation and travel provided free-of-charge by the sponsor or organiser must be **adequate to the purpose of the meeting**, secondary to the purpose of the meeting, and **must not be extended to persons other than the experts and employees of healthcare providers**.

What is forbidden in relation to advertising for MDs and IVDs targeted at experts and employees of healthcare provider?

X In association with advertising for MDs and IVDs, experts and employees of healthcare providers must not require or accept any advantages forbidden by law /i.e. offers, promises or gifts or other benefits, unless these are of insignificant value and are related to the expert activities performed by them/ or such offers, promises or gifts or other benefits that are in conflict with the sponsoring of meetings and scientific congresses.

X If the advertising targeted at experts and employees of healthcare providers is intended as a reminder of the MD or IVD, it **must not** contain any data other than the device trade name or trademark, where applicable.

X Advertising for MDs and IVDs must not, in any way, refer to specific state administration bodies.

!! X X *What is forbidden in association with advertising for MDs and IVDs targeted at experts and employees of healthcare providers?*

X It is **forbidden** to advertise MDs or IVDs fully or partially reimbursed from public health insurance in the form of a consumer competition based on the quantities of prescribed, dispensed or used devices.

X In association with advertising for MDs and IVDs targeted at experts and employees of healthcare providers, it is **forbidden** to offer, promise or provide gifts or other benefits to these persons, unless these are of insignificant value and are related to the expert activities performed thereby.

X It is **forbidden** to advertise products targeting health that are not medicinal products or MDs or IVDs, and do so in a manner suggesting that the product is a medicinal product, MD or IVD.

X Advertising constituting of unfair commercial practice as referred to under Act No 634/1992 Coll., on Consumer Protection, as amended, is **forbidden**.