Information for the General Public Concerning Advertising for Medical Devices and in Vitro Diagnostic Medical Devices

The State Institute for Drug Control hereby provides the general public with answers to questions in order to inform the general public about 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 disseminated particularly via communication media through which advertising is distributed, i.e., media allowing for the transfer of advertising, namely the periodic press and non-periodic publications, radio and television broadcasting, on-demand audiovisual media services, video-sharing platform services, audiovisual production, computer networks, audiovisual media, posters and leaflets.

*What are the **necessary requirements governing advertising for MDs and IVDs** intended for the general public?*

✓It must be formulated in a manner clearly showing that the product is a MD or an IVD.

✓It must contain the trade name of the MD or IVD.

✓It must contain the substance of the intended purpose of use of the MD or IVD.

For therapeutic purposes, e.g.:

- *diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of a disease;*
- *diagnosis, monitoring, treatment, alleviation of, or compensation for an injury or disability;*
- *investigation, replacement or modification of the anatomy or of a physiological or pathological process or state;*
- *providing of information by means of in vitro examination of specimens derived from the human body, including organ, blood, and tissue donations;*
- *devices for the control or support of conception;*
- *products specifically intended for the cleaning, disinfection or sterilisation of devices as referred to in Article 1(4) of Regulation EU 2017/745.*

✓It must contain a clear, in case of printed advertisement well readable, encouragement to carefully read the instructions for use of the MD or IVD as well as information related to its safe use, where it is mandatory to attach such information to the MD or IVD.

✓Where the advertising targeted at the general public is intended as a **reminder of the MD or IVD, it must contain only the trade name or trademark of the MD or IVD.**

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

*What **must not form part of advertising for MDs and IVDs** addressed to the general public?*

✗Advertising for MDs and IVDs must not contain

- texts, names, trademarks, pictures and figurative or other signs that may mislead the user or the patient with regard to the device's intended purpose, safety and performance by
  - ascribing functions and properties to the device which the device does not have;
  - creating a false impression regarding treatment or diagnosis, functions or properties which the device does not have;

- failing to inform the user or the patient of a likely risk associated with the use of the IVD in line with its intended purpose; or
- suggesting uses for the device other than those stated in the intended purpose.

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

✗ The subject of advertising addressed to the general public must not be a MD or an IVD, which is, according to the manufacturer´s instructions, intended solely for use by healthcare professional and which may be dispensed only on order or request form issued by adoctor pursuant to other legal regulations.

✗ Advertising for MDs and IVDs addressed to the general public must not

- give the impression that consultation with a doctor, a medical intervention or treatment are not necessary, particularly through an offer of providing the diagnosis or offer of distance treatment;
- indicate that the clinical performance of the MD and IVD is guaranteed, superior or equal to the efficacy of other treatment or performance of another MD and IVD or that their use is not associated with risks;
- indicate that not using the MD and IVD can adversely affect the condition of health of the persons;
- be focused solely on individuals younger than 15 years of age;
- recommend the MD and IVD with reference to the recommendations of scientists, healthcare professionals or persons who are not scientists or healthcare professionals but who could, due to their actual or supposed social position, support their use;
- refer to the completion of clinical investigations or other processes that are the preconditions for placing the MD or IVD on the market;
- suggest that the safety or efficacy of the MD or IVD is guaranteed solely by it being of natural origin;
- lead to a potentially incorrect self-diagnosis by describing or giving a detailed encounter of how a specific case developed;
- suggest the possibility of cure in an improper, exaggerated or misleading manner;
- use images of alterations of the human body caused by the disease or injury or through the action of the MD or IVD on the human body or its parts in an improper, exaggerated or misleading manner.

✗ Advertising for MDs and IVDs targeted at specialists and employees of healthcare providers must not be freely available to the general public and must not be disseminated outside communication media intended primarily for the former /particularly in specialised publications, specialised printed publications, specialised audiovisual works or in the form of a direct communication with these persons/.

‼ ✗ ✗ *What is **forbidden in association with advertising** for MDs and IVDs addressed to the general public?*

It is forbidden to provide a specimen MD or IVD, which:

- is, according to the manufacturer´s instructions, intended solely for use by a healthcare professional;
- may be dispensed solely on order or request form issued by a doctor.

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