UST-39 version 1 Regulation of Advertising for Medical Devices and in Vitro Diagnostic Medical Devices

This Guideline supersedes Guideline UST-39 as of 31 October 2023.

The Guideline is based upon legislative conditions stipulated by:

- Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (hereinafter referred to as the "MDR")
- Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU (hereinafter referred to as the "IVDR")
- 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")
- Act No 375/2022 Coll., on Medical Devices and in Vitro Diagnostic Medical Devices (hereinafter referred to as "Act No 375/2022 Coll.")
- Act No 48/1997 Coll., on Public Health Insurance and on Amendments to Some Related Acts, as amended (hereinafter referred to as "Act No 48/1997 Coll., on Public Health Insurance")
- Act No 441/2003 Coll., on Trademarks and on Amendments to Act No. 6/2002 Coll. on Courts, Judges, Lay Judges and State Court Administration and on Amendments to Certain Other Acts (Act on Courts and Judges), as amended (hereinafter referred to as "Act No 441/2003 Coll., on Trademarks")
- Act No 89/2012 Coll., the Civil Code, as amended (hereinafter referred to as "Act No 89/2012 Coll., the Civil Code")
- Act No 634/1992 Coll., on Consumer Protection, as amended, (hereinafter referred to as "Act No 634/1995 Coll., on Consumer Protection")
- Decree No 377/2022 Coll., implementing some provisions of the Act on Medical Devices and in Vitro Diagnostic Medical Devices (hereinafter referred to as "Decree No 377/2022 Coll.")

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)") falling within the powers of the State Institute for Drug Control (hereinafter referred to as the "Institute").

The Guideline explains terms and provides the positions of the Institute on advertising for MDs and IVDs. The Guideline is of recommendatory nature and to facilitate navigation within the particular areas, the text contains references to the legislation stipulating the relevant terms. As the area concerning MDs and IVDs is rather extensive, the text may not provide answers to your particular case; for this reason, please do not hesitate to contact the Medical Device Advertising Surveillance Unit of the Medical Device Regulation Section via e-mail at drzp@sukl.cz, where your question will be answered. Information on advertising for MDs and IVDs is also available from https://www.niszp.cz/cs/dozor-nad-reklamou.

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I. Term definition specification

*"In general, **advertising** shall mean 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, unless specified otherwise below."*

Relevant provisions: Section 1(2) of Act No 40/1995 Coll., on Advertising Regulation

***"Advertising for medical devices and in vitro diagnostic medical devices** 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 attended 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*."

Relevant provisions: Section 5k(1) of Act No 40/1995 Coll., on Advertising Regulation

"*In the labelling, instructions for use, making available, putting into service **and advertising of devices, it shall be prohibited to use text, 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:*

a) ascribing functions and properties to the device which the device does not have;
b) creating a false impression regarding treatment or diagnosis, functions or properties which the device does not have;
c) failing to inform the user or the patient of a likely risk associated with the use of the device in line with its intended purpose;
d) suggesting uses for the device other than those stated to form part of the intended purpose for which the conformity assessment was carried out."

Relevant provisions: Article 7 of the MDR

Pursuant to the provision of Section 7(b) of Act No 40/1995 Coll., on Advertising Regulation, the Institute is the authority competent to carry our surveillance over advertising for MDs and IVDs and sponsoring in this area in the Czech Republic **except for** advertising disseminated via radio and television broadcasting and via on-demand audio-visual media services and video-sharing platform services and for sponsoring in radio and television broadcasting and in on-demand audio-visual media services, and in video-sharing platform services. Furthermore, the Institute is the authority competent to carry our surveillance over compliance with Article 7 of the MDR within the scope relevant to advertising for medical devices, and Article 7 of the IVDR within the scope relevant to advertising for in vitro diagnostic medical devices.

Surveillance over advertising disseminated via radio and television broadcasting and via on-demand audio-visual media services and video-sharing platform services and for sponsoring in radio and television broadcasting and in on-demand audio-visual media services, and in video-sharing platform services concerning MDs and IVDs is carried out by the Council for Radio and Television Broadcasting. An overview of other authorities competent to carry out surveillance over compliance with advertising regulation in other fields and areas is available from: https://www.niszp.cz/cs/dozor-nad-reklamou.

The law is applicable to persons placing, processing and disseminating advertising as well as healthcare professional and employees of healthcare providers, e.g., in case they attend sponsored or promotional events (meetings of experts, scientific conferences, congresses, etc.), use promotional samples, and provide promotional materials about MDs or IVDs to patients.

*"For the purposes of this Act, a **medical device** shall mean a medical device as defined by Art. 2(1) of the Medical Device Regulation, accessory for a medical device as defined by Art. 2(2) of the Medical Device Regulation, and a product referred to under Annex XVI to the Medical Device Regulation.*

*For the purposes of this Act, an **in vitro diagnostic medical device** shall mean an in vitro diagnostic medical device as defined by Art. 2(2) of the In Vitro Diagnostic Medical Device Regulation or its accessory as defined by Art. 2(4) of the In Vitro Diagnostic Medical Device Regulation.*

*For the purposes of this Act, a **device** shall mean a medical device and an in vitro diagnostic medical device."*

Relevant provisions: Section 2 of Act No 375/2022 Coll.

*"A **medical device** means any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the following specific medical purposes:*

- *diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of 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 information by means of in vitro examination of specimens derived from the human body, including organ, blood and tissue donations, and which **does not achieve** its principal intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its function by such means.*

The following products shall also be deemed to be medical devices:

- *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 the MDR and of those referred to in the first paragraph of this point."*

Relevant provisions: Article 2(1) of the MDR

*"**Accessory** for a medical device **(hereinafter referred to as "MD accessory")** - an article which, whilst not being itself a medical device, is intended by its manufacturer to be used together with one or several particular medical device(s) to specifically enable the medical device(s) to be used in accordance with its/their intended purpose(s) or to specifically and directly assist the medical functionality of the medical device(s) in terms of its/their intended purpose(s)."*

Relevant provisions: Article 2(2) of the MDR

Product referred to under Annex XVI to the MDR (hereinafter referred to as "product") - LIST OF GROUPS OF PRODUCTS WITHOUT AN INTENDED MEDICAL PURPOSE REFERRED TO IN ARTICLE 1(2)

"1. Contact lenses or other items intended to be introduced into or onto the eye.

2. Products intended to be totally or partially introduced into the human body through surgically invasive means for the purpose of modifying the anatomy or fixation of body parts with the exception of tattooing products and piercings.

3. Substances, combinations of substances, or items intended to be used for facial or other dermal or mucous membrane filling by subcutaneous, submucous or intradermal injection or other introduction, excluding those for tattooing.

4. Equipment intended to be used to reduce, remove or destroy adipose tissue, such as equipment for liposuction, lipolysis or lipoplasty.

5. High intensity electromagnetic radiation (e.g. infra-red, visible light and ultra-violet) emitting equipment intended for use on the human body, including coherent and non-coherent sources, monochromatic and broad spectrum, such as lasers and intense pulsed light equipment, for skin resurfacing, tattoo or hair removal or other skin treatment.

6. Equipment intended for brain stimulation that apply electrical currents or magnetic or electromagnetic fields that penetrate the cranium to modify neuronal activity in the brain."

Relevant provisions: Annex XVI to the MDR

"In vitro diagnostic medical device (hereinafter referred to as "IVD") *means any medical device which is a reagent, reagent product, calibrator, control material, kit, instrument, apparatus, piece of equipment, software or system, whether used alone or in combination, intended by the manufacturer to be used for the in vitro examination of specimens, including blood and tissue donations, derived from the human body, solely or principally for the purpose of providing information on one or more of the following:*

- *concerning a physiological or pathological process or state,*
- *concerning congenital physical or mental impairments,*
- *concerning the predisposition to a medical condition or a disease,*
- *to determine the safety and compatibility with potential recipients,*
- *to predict treatment response or reactions,*
- *to define or monitor therapeutic measures.*

Specimen receptacles shall also be deemed to be in vitro diagnostic medical devices.

A receptacle of a vacuum or other type intended by the manufacturer solely for the primary storage and keeping of specimen derived from the human body for the purposes of in vitro diagnostic examination is also deemed to be an in vitro medical device. Products for general laboratory use are not in vitro diagnostic medical devices as long as they are not, with respect to their qualities, intended by the manufacturer solely for in vitro diagnostic examination."

Relevant provisions: Article 2(2) of the IVDR,
Section 2(2) and Section 2(3) of Act No 375/2022 Coll.

Expert – a person authorised to prescribe or dispense MDs or IVDs.

The Institute has issued a recommendatory guideline on the term "expert" as referred to under Section 2a of Act No 40/1995 Coll., on Advertising Regulation, available from https://www.niszp.cz/cs/dozor-nad-reklamou, and Guideline UST-40.

Relevant provisions: Section 2a of Act No 40/1995 Coll., on Advertising Regulation

"*Trademark* *– under the conditions set forth by the Act on Trademarks, it may be any mark, particularly words, incl. personal names, colours, drawings, letters, numerals, product shape or packaging or sounds, as long as such mark is capable of*

- *distinguishing products or services of one person from the products or services of another person; and*
- *being represented in the Trademark Registry (hereinafter referred to as the "Registry") in a manner that allows competent authorities and the public to clearly and precisely indicate the subject of the protection provided to the trademark owner."*

Relevant provisions: Section 1a of Act No 441/2003 Coll., on Trademarks

"Communication media *– media through which advertising is disseminated – media that allow for the transfer of advertising, particularly the periodic press and non-periodic publications, radio and television broadcasting, on-demand audiovisual media services, video-sharing platform services, audio-visual production, computer networks, audio-visual media, posters and leaflets."*

Relevant provisions: Section 1(3) of Act No 40/1995 Coll., on Advertising Regulation

Insignificant value – the specification of the term is based upon a guideline issued by the Institute as Guideline UST-27, Section 6(b) of which stipulates: "*Up to 1,500,-CZK/year/expert and the necessity to be related to the performed expert activity; both conditions must be met at the same time. Any gift, incl. sponsor gift, the value of which exceeds 500,- CZK, is subject to the Act on Income Tax*".

Relevant provisions: Institute´s Guideline UST-27 available from: https://www.sukl.cz/sukl/obecne-pokyny-a-formulare

Many products the purpose of which is to exert positive influence upon the human organism and to facilitate its proper functioning (such as medicinal products or medical devices) or products presented as those having therapeutic or preventive properties are traded in the Czech Republic. In respect of such products, the Institute assesses whether the product is another product (e.g., food or cosmetic product, etc.), or whether it is a product the classification of which is disputable. With a view to the fact that individual types of products

differ from each other in their intended purpose, intensity, mechanism of their action upon the human body, and the risks associated therewith when the product is used, consistent distinction of the products is necessary. The primary basis for any procedures in this area must be public health protection. Where a breach of the Act on Advertising Regulation is suspected for a product other than a medicinal product or an MD or IVD, the Institute forwards the findings to the competent administrative authority. In case of a disputable product classification, on the basis of the provision of Section 5(2)(f) and Section 6(1) of Act No 375/2022 Coll., the Institute "*shall decide whether a product is governed by the Medical Device Regulation or by the In Vitro Diagnostic Medical Device Regulation, and shall do so either upon request or ex-officio".* The Act on Advertising Regulation must be observed also by persons authorised to dispense MDs and IVDs.

The manufacturer, its authorised representative, importer, distributor is obliged to notify MDs and IVDs placed or made available on the market within the territory of the Czech Republic pursuant to the transitional provision of Section 74(8) of Act No 375/2022 Coll.

The list of notified MDs and IVDs is available from the Registry of Medical Devices (RZPRO) on the Institute´s website under the Medical Devices tab at https://www.niszp.cz/registr-zdravotnickych-prostredku or also at https://eregpublicsecure.ksrzis.cz/Registr/RZPRO. At present, it is possible to search the Eudamed only for economic operators registered pursuant to the MDR, who registered on a voluntary basis - https://ec.europa.eu/tools/eudamed/#/screen/search-eo. Once the fully functional Eudamed database is put into live production, economic operators will be obliged to register in the Actor module as per Article 31 of the MDR and manufacturers will be obliged to register the devices in the UDI database as per Article 29 of the MDR. More detailed information on the registration of persons and on the notification of MDs and IVDs is available from https://www.niszp.cz/cs/otazky-odpovedi-odboru-registrace-notifikace/registrace-notifikace-od-ucinnosti-mdr-ivdr and https://www.niszp.cz/cs/ohlasovaci-povinnost-distributoru-v-rzpro-do-spusteni-iszp.

II. General requirements governing advertising

Advertising must meet all of the requirements laid down by the law, avoiding, in particular, advertising constituting **unfair commercial practices** or **surreptitious advertising** or **advertising contrary to accepted principles of morality**. Advertising constituting both unfair commercial practice or surreptitious advertising can significantly affect the perception of the communicated information by an ordinary user and particularly in case of advertising for MDs and IVDs, incorrect understanding of the information by the patient – consumer can have a substantially negative impact on the use of MDs and IVDs and on the health of patients.

Effective legal regulations set forth also requirements for comparative advertising:

***"Comparative advertising** indicates, directly or indirectly, another competitor or its goods or service.*

Generally, comparative advertising is permissible in terms of comparison, as long as it

- *is not misleading,*
- *compares only goods and services meeting the same need or intended for the same purpose,*
- *objectively compares one or more substantial, important, verifiable, and typical properties of the goods or services, incl. price,*
- *compares goods with designation of origin solely with goods with the same designation,*
- *does not downplay the competitor, its position, its operation or outcomes thereof and does not unfairly profit therefrom, and*
- *does not offer goods or services imitating or reproducing goods or services covered by a competitor´s trademark or name".*

***"Comparative advertising for MDs and IVDs** shall be permissible if it meets the conditions set forth by the Civil Code and targets persons authorised to prescribe or dispense such MDs or IVDs."*

Relevant provisions: Section 2980 of Act No 89/2012 Coll., the Civil Code,
Section 2(2) and Section 2a of Act No 40/1995 Coll., on Advertising Regulation

***"Commercial practice** means the way the seller behaves, comprising actions, omissions, statements, business communication, including advertising and placement on the market associated with promotion, sale or delivery of the product or service to the consumer."*

Relevant provisions: Section 2(1)(o) **of Act No** 634/1995 Coll., on Consumer Protection

***"Unfair commercial practice,** a commercial practice is unfair if it is in conflict with the requirements of expert care and materially distorts or can materially distort the economic behaviour of the consumer whom it targets or who is exposed to its effects in relation to the product or service. Where the commercial practice targets a particular consumer group, it is assessed on the basis of an average member of such group.*

- Commercial practices which are likely to materially distort the economic behaviour of a particular, clearly identifiable group of consumers who are particularly vulnerable to the practice or the underlying product or service because of their mental or physical infirmity, age or credulity in a way which the trader could reasonably foresee, shall be assessed from the perspective of the average member of that group; this is without prejudice to the common and legitimate advertising practice of making exaggerated statements or statements which are not meant to be taken literally.

*- Unfair commercial practice constitutes especially **deceptive activity** or **deceptive omission** and **aggressive commercial practice**.*

The use of an unfair commercial practice prior to the decision concerning the purchase, in the course of the decision-making, and after the decision is made is forbidden."

Relevant provisions: Section 4 of Act No 634/1995 Coll., on Consumer Protection

***"Surreptitious advertising** – such advertising means advertising in respect of which it is difficult to distinguish that it constitutes advertising, primarily because it is not labelled as advertising. Advertising must not pretend to be other methods of dissemination of information (expert paper, journalist coverage, etc.) than advertising. Surreptitious advertising is, for instance, advertising presented in the form of a journalist coverage, interview, expert article, educational material or non-promotional website, etc., where the labelling, classification or structure of the print material does not clearly show that it constitutes advertising. For example, it is not sufficient to distinguish advertising only by the print background colour or by placing it as a footnote, etc. The selected method of distinguishing advertising from other editorial communications is within the powers of the print publisher and it should be typical for the print publication in question and clear enough for the addressee of the advertising, e.g., introduced by a title "Advertising" or "Promotion".*

Surreptitious advertising evokes a feeling of the consumer-patient that it is e.g., an expert article, a personal story, etc. and does not give him/her the freedom not to follow the advertising (to eliminate it) or to be reasonably wary, cautious, and watchful in relation to the presented information."

Relevant provisions: Institute´s Guideline UST-27 available from https://www.sukl.cz/sukl/obecne-pokyny-a-formulare

***"Advertising must not be contrary to accepted principles of morality**, it must not, in particular, contain any discrimination by race, gender or nationality or attack religious or national sentiments, jeopardise morality in a generally unacceptable way, diminish human dignity, contain elements of pornography, violence or elements exploiting the motifs of fear. Advertising must not attack political affinity."*

Advertising exploiting the motifs of fear is such advertising that evokes fear or concerns in the consumer as a result of which the consumer may make a commercial decision that he/she would not make otherwise. *The aforementioned list is only demonstrative (illustrative).*

Relevant provisions: Section 2(3) of Act No 40/1995 Coll., on Advertising Regulation

"Advertising must not encourage behaviour harmful for the health or jeopardising the safety of persons or property or behaviour harmful for the interests of environmental protection."

Relevant provisions: Section 2(4) of Act No 40/1995 Coll., on Advertising Regulation

"With regard to persons under the age of 18 years, advertising must not

- *encourage behaviours jeopardising their health, mental or moral development,*
- *exploit their special trust towards their parents or guardians or other persons,*
- *inappropriately represent them in dangerous situations."*

Relevant provisions: Section 2c of Act No 40/1995 Coll., on Advertising Regulation

"Generally, it is forbidden to disseminate unsolicited advertising in paper form if it is harassing the addressee; harassing advertising is deemed to be advertising targeted at a particular addressee who had previously clearly and understandably expressed his wish that the unsolicited advertising be not disseminated to him/her."

Relevant provisions: Section 2(1)(c) of Act No 40/1995 Coll., on Advertising Regulation

"Advertising constituting an unfair commercial practice pursuant to special legal regulation is generally forbidden."

Relevant provisions: Section 2(1)(b) of Act No 40/1995 Coll., on Advertising Regulation

"Advertising disseminated at publicly accessible places outside the premises in a manner other than via an advertising or promotional equipment established pursuant to special legal regulation is generally forbidden."

Relevant provisions: Section 2(1)(d) of Act No 40/1995 Coll., on Advertising Regulation

III. Requirements governing advertising for MDs and IVDs

The requirements governing advertising for MDs and IVDs are primarily based upon the requirements for the placement of MDs and IVDs on the market pursuant to effective legislation. As numerous persons engaged in advertising have gained experience with advertising for medicinal products, they often apply experience from this area also to advertising for MDs and IVDs. Nevertheless, there are substantial differences, both in terms of legislation and division of MDs and IVDs to risk classes, lists and the differences implied thereby for the placing, processing, and dissemination of advertising for MDs and IVDs. The law distinguishes between advertising for MDs and IVDs intended for the general public and that targeting experts.

The subject of advertising may only be an MD that may be placed on the market in compliance with the MDR or an IVD that may be placed on the market in compliance with the IVDR and Act No 375/2022 Coll. – publicly available from https://www.niszp.cz/legislativa.

The list of notified MDs and IVDs is available from the RZPRO registry on the Institute´s website under the Medical Devices tab at https://www.niszp.cz/index.php/cs/registr-zdravotnickych-prostredku or also at https://eregpublicsecure.ksrzis.cz/Registr/RZPRO. Data about MDs will begin to be entered into the Eudamed database from the date it becomes fully functional. The timelines for the fulfilment of the obligation implied by Article 29 of the MDR are laid down by Art. 123(d) of the MDR. At present, it is possible to search the Eudamed only for those economic operators who registered on a voluntary basis - https://ec.europa.eu/tools/eudamed/#/screen/search-eo.

Relevant provisions: Section 5k(3) of Act No 40/1995 Coll., on Advertising Regulation
Recital 44 of the MDR

"A medical device, which does not meet the conditions for placement on the market stipulated by the MDR, may be presented or demonstrated only at trade fairs, exhibitions and demonstration or similar events providing it is labelled in compliance with Art. 21(3) of the MDR."

"An in vitro diagnostic medical device, which does not meet the conditions for placement on the market stipulated by the IVDR, may be presented or demonstrated only at trade fairs, exhibitions and demonstration or similar events providing it is labelled in compliance with Art. 19(3) of the IVDR."

Relevant provisions: Section 5k(4), Section 5k(5) of Act No 40/1995 Coll., on Advertising Regulation

"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."

Relevant provisions: Section 5k(6) of Act No 40/1995 Coll., on Advertising Regulation

***"A consumer competition** shall mean a competition, poll or another prize event organised for consumers in direct relation to promotion, offer or sale of a product or service of the seller in which the seller or a person authorised thereby undertakes to disburse to randomly selected competitors monetary or non-monetary prizes and participation in which is preconditioned by purchase of a particular product or service and evidencing this purchase to the seller or conclusion of a contractual relationship with the seller of the product or service or consumer´s participation in the seller´s marketing event, incl. indirectly, via another person."*

Relevant provisions: Section 2(1)(v) of Act No 634/1995 Coll., on Consumer Protection

"Advertising for MDs and IVDs must not in any way refer to specific state administration bodies."
Relevant provisions: Section 5k(7) of Act No 40/1995 Coll., on Advertising Regulation

Internet advertising – internet advertising is governed by the same rules as those governing other forms and means allowing to disseminate advertising. On the internet, it is permissible to disseminate information about MDs and IVDs as long as this information is accessible on the website only to those who search for it themselves, i.e., a website promoting MDs and IVDs must meet the requirements of the law, always targeting specific persons, either the general public, or the experts. Access to advertising targeting experts or employees of healthcare providers must be secured so as to ensure that it will be visited mostly by these persons, at least by means of a statement of being an expert or employee of a healthcare provider, confirmation of being familiar with the definition of an expert or employee of healthcare provider, and confirmation of being familiar with the risks a person other than an expert or employee of a healthcare provider becomes exposed to upon entering a website intended primarily for the former. Although Act No 40/1995 Coll., on Advertising Regulation does not clearly specify the requirement whether advertising for MDs and IVDs in the form of verbal promotion via a computer network and a video placed therein must be accompanied also by written information; nevertheless, the Institute recommends that the video be accompanied by a written notice and the necessary information, also with a view to potential interest in the concerned MD or IVD, as the information on the MD provided merely in verbal form can be misinterpreted by the general public, while written information in the video can be stopped and the audience can take enough time to read it, even repeatedly. Furthermore, with a view to targeting the advertising to the general public, where the video will be available to various age groups, it is also necessary to comply with the provisions of Section 2c and Section 5l(4)(d) of Act No 40/1995 Coll., on Advertising Regulation and to present the MDs and IVDs in the video in a manner ensuring that this requirement of the law is met.

Educative and informative data about human health or diseases are not considered advertising as long as they do not include any reference to a specific MD or IVD, incl. an indirect one. Materials containing indirect references are governed by the Act and the surveillance authority then assesses such materials from the perspective of this Act. Such material becomes advertising at the moment when it is possible to apply the definition of advertising as referred to under Section 1(2) or Section 5k(1) of Act No 40/1995 Coll., on Advertising Regulation thereto. A material the exclusive purpose of which is to provide complete and objective information about available treatment, without directly or indirectly promoting any specific MD or IVD, shall not be deemed to be advertising. Sales catalogues and pricelists of MDs and IVDs, as long as they contain only the basic description of the properties of the MDs and IVDs necessary for their identification, shall not be considered to be advertising, either.
Relevant provisions: Section 5k(2)(b), Section 5k(2)(c) of Act No 40/1995 Coll., on Advertising Regulation

IV. Advertising for MDs and IVDs intended for the general public

The purpose of requirements governing advertising for MDs and IVDs intended for the general public is to ensure proper provision of information to the general public and to prevent dissemination of information that is untrue, exaggerated, misleading or manipulative and that initially cannot be assessed by the general public due to their credulity and, many times, insufficient expertise concerning a particular disease.

Advertising for MDs or IVDs intended for the general public "*must be formulated in a manner clearly showing that the product is an MDs or an IVD; it must contain the tradename and the substance of the intended purpose. Furthermore, it must contain a clear, in case of printed advertisements 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 pursuant to another legal regulation."* */To meet the requirement according to which advertising targeting the general public must advise that it concerns an MD or an IVD, it is ideal to use the phrases "medical device" or "in vitro diagnostic medical device", as the general public is well familiar with these terms and there will be no doubt as to what product is the subject of the advertising. Formulation of the substance of the intended purpose must be based upon the data issued by the manufacturer within the process of conformity assessment for the MD or IVD which is the subject of the advertising. The time of issuance of the declaration of conformity for the MD or IVD which is the subject of the advertising must be in accordance with the time of the placement, processing of the advertising. Where the intended purpose is broad, the substance of the intended purpose may be*

complemented with a warning that the intended purpose of the MD or IVD is broader and will be made available upon request, through a reference, etc. When formulating the statement urging to carefully read the Instructions for Use of the MD or IVD and the information related to its safe use, both of the aforementioned requirements must be met. Should this statement and information be replaced with a reference to FAQs, it will be considered insufficient, even if these form part of the advertising./

Relevant provisions: Section 5l(3) of Act No 40/1995 Coll., on Advertising Regulation

"*Advertising for MDs and IVDs intended for 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; /This concerns offers of an intermediary service, especially via the internet. A statement of good condition of health, e.g., in the form of an affidavit, or an internet consultation with a "physician" are not sufficient, not even where internet forms are used. As electronic signature is not required, the veracity of such statements cannot be guaranteed, not even partially./,*
- *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 /Advertising must not suggest that the effects of a product are equal or superior to another product, which is implied by the aforementioned ban on comparative advertising targeting the general public. Although certain exaggeration is envisaged in advertising, in advertising for MDs and IVDs, such exaggeration should be avoided/,*
- *indicate that not using the MD and IVD can adversely affect the condition of health of people /Although MDs and IVDs help prevent or diagnose a disease or symptoms thereof or serve as an aid for the treatment of a disease, but generally, they cannot guarantee a better condition of health. This provision of the Act is aimed primarily at preventing overuse or inappropriate use of MDs and IVDs/,*
- *focus solely on individuals younger than 15 years of age /Persons younger than 15 years of age often cannot responsibly use many MDs and IVDs on their own, without supervision by responsible persons, and advertising must not be directed towards such persons using MDs and IVDs/,*
- *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 /Doctors, renowned experts, chairs of professional chambers or representatives of professional societies, but also e.g., artists, actors, presenters, sportsmen, singers, politicians or parents may not appear in advertisements for MDs and IVDs. Due to their actual or assumed social position, professional societies of experts could encourage the consumption of MDs and IVDs, and for this reason, they cannot recommend them in advertisements./,*
- *refer to the completion of clinical investigations or other processes that are the preconditions for placing the MD or IVD on the market /The general public does not have sufficient expert knowledge or experience to be able to assess such data or statements. Pursuant to Chapter VII(I)(83) of the MDR, post-marketing studies and consumer surveys form part of the manufacturer´s post-marketing surveillance systems for MDs and the aforementioned is also, i.a., a condition of updates to clinical investigations for MDs./,*
- *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 /This provision of the Act does not prejudice freedom of speech, therefore, it is possible for a particular person to share his/her feelings and impressions with the public, but never in association with advertising or for the purposes of advertising for MDs and IVDs/,*
- *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 /These provisions concern unfair commercial practices and exaggerations in advertising. Potential illustrative images documenting the efficacy of MDs and IVDs must not be repulsive and upon request, the advertiser must be able to evidence the claimed treatment success rate. In advertising, MDs and IVDs may be attributed only such effects that have been scientifically verified, clinically evaluated in*

the final report from a clinical investigation or in a performance study, whereas giving a false impression about the possibilities of cure thanks to the use of the device is not allowed./."

Relevant provisions: Section 5l(4) of Act No 40/1995 Coll., on Advertising Regulation

The subject of advertising addressed to the general public "*may only be an MD or an IVD, which is not, according to the manufacturer´s instructions, intended solely for use by healthcare professionals and the dispensing of which is not restricted to order or request form issued by the physician pursuant to other legal regulations. Where the advertising targeted at the general public is intended as a reminder of the MD or IVD, it must contain only the tradename or trademark of the MD or IVD."*

Relevant provisions: Section 5l(1), Section 5l(5) of Act No 40/1995 Coll., on Advertising Regulation

MDs the dispensing of which is restricted to order or request form issued by a physician fall within the List of groups of devices that may jeopardise the lives or health of people.

Groups of devices that may jeopardise the lives or health of people, even if used in compliance with their intended purpose, if not used under physician's supervision, and which are dispensed on medical prescription only, are

- intrauterine devices,
- devices to treat breathing disorders in sleep,
- implantable devices applied by injection,
- hearing aids, and
- contact lenses if used in children under the age of 15 years.

Relevant provisions: Section 8 of Decree No 377/2022 Coll.

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

Relevant provisions: Section 5k(7) of Act No 40/1995 Coll., on Advertising Regulation

"*The provision of samples of such MDs or IVDs to the general public that are, according to the manufacturer´s instructions, intended solely for use by a healthcare professional and that may be dispensed only on order or request form issued by the physician pursuant to other legal regulations is forbidden."*

Relevant provisions: Section 5l(2) of Act No 40/1995 Coll., on Advertising Regulation

The provision of promotional samples of MDs and IVDs is detailed in Guideline UST-41.

V. Advertising for MDs and IVDs targeted at experts

The purpose of requirements governing advertising for MDs and IVDs targeted at experts (persons authorised to prescribe or dispense MDs or IVDs) and employees of healthcare providers is to help experts and employees of healthcare providers to better navigate in this quickly growing area and to prevent excessive influencing of experts and employees of healthcare providers in terms of the use, prescribing and sale of MDs and IVDs.

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 audio-visual 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 on the clinical benefit, safety, and performance of the specific medical device or in vitro diagnostic medical device; data taken over from specialised publications or from specialised printed publications must be accurately reproduced and their source cited. /The formulations meeting this requirement must be based upon the data issued by the manufacturer in the process of conformity assessment for the MD or IVD which is the subject of the advertising. The time of issuance of the declaration of conformity for the MD or IVD which is the subject of the advertising must be in accordance with the time of the placement, processing of the advertising. Article 2(53) of the MDR stipulates: "For the purposes of this Regulation, 'clinical benefit' means the positive impact of a device on the health of an individual, expressed in terms of a meaningful, measurable, patient-relevant clinical outcome(s), including*

outcome(s) related to diagnosis, or a positive impact on patient management or public health". Article 2(22) of the MDR stipulates: "For the purposes of this Regulation: 'performance' means the ability of a device to achieve its intended purpose as stated by the manufacturer". In the context of advertising, the requirement for safety will be met by the provision of the CE mark, as issued by the manufacturer or a declaration of conformity for the MD or IVD which is the subject of the advertising./.

Specialised printed publications are specialised journals intended for experts or employees of healthcare providers. The advertising materials must clearly indicate that they are not intended for the general public. Generally, internet cannot be considered a communication media intended primarily for experts or employees of healthcare service providers. Where advertising targeted at experts and employees of healthcare providers is in the format of a website, such website must be secured in a manner ensuring that it will be visited mostly by experts and employees of healthcare providers, at least by means of a statement that a person entering such website is an expert within the meaning of law or an employee of a healthcare provider and a confirmation that the person entering the website is familiar with the statutory definition of an expert, employee of healthcare service provider and the risks a person other than an expert or employee of a healthcare provider becomes exposed to upon entering a website intended primarily for experts and employees of healthcare providers. The provided information on the definition of an expert, employee of a healthcare provider and on potential risks must be worded in a manner minimising the risk of incorrect or misleading interpretation.

Where advertising for MDs and IVDs targeted primarily at experts and employees of healthcare providers is disseminated via the internet, it must be ensured that no one who does not actively search for information on the particular MD or IVD and is not interested in the concerned MD or IVD is actively offered this information, because such advertising would be classified as advertising intended for the general public. And such advertising would have to meet the requirements of the law governing advertising intended for the general public.

Relevant provisions: Section 5m(1) of Act No 40/1995 Coll., on Advertising Regulation

"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."

Relevant provisions: Section 5m(4) of Act No 40/1995 Coll., on Advertising Regulation

"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."

Relevant provisions: Section 5m(2) of Act No 40/1995 Coll., on Advertising Regulation

Insignificant value – the specification of the term is based upon a guideline issued by the Institute as Guideline UST-27, Section 6(b) of which stipulates: "*Up to 1,500,-CZK/year/expert and the necessity to be related to the performed expert activity; both conditions must be met at the same time. Any gift, incl. sponsor gift, the value of which exceeds 500,- CZK, is subject to the Act on Income Tax*".

Relevant provisions: Institute´s Guideline UST-27 available from: https://www.sukl.cz/sukl/obecne-pokyny-a-formulare

"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 that the device tradename or trademark, where applicable."

Relevant provisions: Section 5m(5) of Act No 40/1995 Coll., on Advertising Regulation

Advertising for MDs and IVDs that may be targeted only at experts and employees of healthcare providers are visits of sales representatives. During each visit conducted for the purposes of advertising for MDs and IVDs, the sales representative is obliged to provide the visited expert or employee of a healthcare service provider with information consistent with information issued by the manufacturer of the MD or IVD in question. A sales representative's visit is understood to be a form of advertising consisting of a personal

presentation of an MD or IVD as a product of particular characteristics and quality. A sales representative is an agent of the manufacturer, authorised representative, importer or distributor, who has the relevant qualification and who will provide the expert or employee of a healthcare service provider with all of the necessary information.

Employee of a healthcare provider – this is a person who uses MDs and IVDs in direct relationship with and during the provision of health care at a healthcare provider as per the relevant expert qualification and expert competences stipulated by the legislation. Furthermore, it is a person who selects, orders and procures MDs and IVDs for the healthcare provider.

The provision of promotional samples of MDs and IVDs is detailed in the Institute´s recommendatory Guideline UST-41.

The sponsoring and provision of gifts and other benefits to experts and employees of healthcare providers in association with MDs and IVDs is detailed in recommendatory Guideline UST-42.

VI. Entities responsible for advertising

Advertiser – *"a legal or natural person who ordered advertising with another legal or natural person."*

Person processing advertising – *"a legal or natural person who processed advertising for itself or for another legal or natural person. If the person processing advertising processes advertising for itself, for the purposes of this Act, it is also the advertiser."*

Person disseminating advertising – *"a legal or natural person publicly disseminating advertising."* The term person disseminating advertising includes all persons publishing or forwarding advertising. These are, in particular, entities publishing printed periodicals or non-periodic publications (journals, newspapers, etc.); sales representatives; physicians where advertising published within the premises of their waiting rooms and offices and provision of advertising materials directly to the patients are concerned; pharmacists, where e.g., advertising published within the premises of the pharmacy is concerned.

Public dissemination is dissemination of advertising at public places, such as waiting rooms, means of transport, places intended for the promotion of products – billboards, citylights, and other advertising areas, printed matter of all kinds – advertising leaflets, periodicals and non-periodic publications, etc. A single person can be the advertiser as well as the person processing the advertising as well as the person disseminating the advertising, i.e., not always these are three different entities.

Relevant provisions: Section 1(5–7) of Act No 40/1995 Coll., on Advertising Regulation

The responsibilities of the advertiser, the person processing advertising, and the person disseminating advertising vary. The law stipulates responsibility for the content and for the methods of dissemination of advertising.

a) *"Responsibility for the content of the advertising lies with the person processing advertising, specifically:*
   - *within full scope, if it created the advertising for its own needs (the advertiser and the person processing advertising is a single person);*
   - *jointly and severally with the advertiser, if it created the advertising for the needs of the advertiser,*
   - *the person processing advertising is fully released from responsibility for the content of advertising in cases where the advertising contains such data specified by the advertiser in respect of which the former is not able to assess their veracity despite all reasonable efforts. With a view to the conditions under which it is possible to exercise this exemption, it is obvious that it does not apply to data that are, in relation to advertising, clearly listed by law and specified as particulars of advertising. Nevertheless, it may apply to cases when advertising contains e.g., an expert claim that is not true or fully consistent with the Instructions for Use of the MD or IVD, and the person processing the advertising is not an expert. In case of a person processing advertising who works on a contractual basis for an advertiser, it is advisable to specify the issues of responsibility in the conditions of the contract.*

b) *Responsibility for dissemination of advertising lies solely with the person disseminating advertising. The person disseminating advertising is fully responsible for its dissemination also in case the*

advertiser has agreed to a method or form of dissemination which is in conflict with the law and such method or form is covered by the contract.

c) *The advertiser is released from responsibility for the content of disseminated advertising which is in conflict with the law, if the advertiser evidences that the person processing the advertising failed to observe the former´s instructions in its processing, due to which the content of the advertising is in conflict with the law. The person processing advertising cannot be released from responsibility for the content of the disseminated advertising by reference to its specification by the advertiser, lest it concerns data the veracity of which the person processing the advertising is not able to assess despite all reasonable efforts (see above).".*

d) *"A recipient of sponsor contribution is responsible for its use in compliance with the Act on Advertising Regulation; i.e., if sponsoring by the sponsor is carried out via another legal or physical person, the provisions of the Act on Advertising Regulation shall be applicable to this person´s activities."*

Relevant provisions: Section 6b of Act No 40/1995 Coll., on Advertising Regulation

The law stipulates obligations of advertisers, persons processing advertising as well as persons disseminating advertising constituting cooperation with the surveillance authority in the conduct of surveillance.

"The advertiser shall be obliged to:

a) *provide, upon request of the Institute, data about the person processing advertising and the person disseminating advertising for the purposes of an administrative procedure. The requested data shall mean, in particular:*

- *the company and registered office of the persons processing and disseminating all forms of this advertising,*
- *and, at the same time, if a contract on advertising processing or dissemination has been concluded by and between the advertiser and other persons, also the date as at which such contract has been concluded;*

b) *provide, upon request of the Institute, further information, e.g., about the purpose and method of advertising dissemination, information about used communication media, target groups of the advertising, time period or plan of dissemination and the used resources and other materials related to the advertising in full;*

c) *keep an example (copy) of each advertising for the minimum period of 5 years of the date the advertising was last disseminated and, in case an administrative procedure is initiated, keep such example until the final decision in the matter; with a view to the potential use of the example of the advertising during the provision of evidence in the administrative procedure, it is advisable to keep not only a copy, but rather specimen advertising in the form in which it was disseminated. Upon written request of the Institute, the advertiser shall be obliged to submit the example of the advertising, and do so free of charge; the requested specimen advertising (examples of advertising) shall mean samples of published advertising (printed advertisements in periodicals and in non-periodic publications, in print, advertising in electronic format, internet promotion, promotional sample, questionnaire used in a marketing study, etc.)."*

"Upon request of the surveillance authority, the person processing advertising shall be obliged to provide data about the advertiser and about the person disseminating the advertising in question for the purposes of an administrative procedure.

The person disseminating advertising shall be obliged to

a) *inform the person who evidences its legitimate interest who the advertiser and the person processing the advertising is;*

b) *upon request of the Institute, for the purposes of an administrative procedure, provide data about the person who ordered dissemination of the advertising with the former; the person who ordered dissemination of the advertising with the person disseminating advertising is typically the advertiser or the person processing advertising; nevertheless, it can be a third party doing so on the basis of an agreement, contract with the advertiser or person processing the advertising."*

Relevant provisions: Section 7a of Act No 40/1995 Coll., on Advertising Regulation

VII. Overview of offences and fines for breaches of requirements governing advertising for MDs and IVDs pursuant to Act No 40/1995 Coll., on Advertising Regulation

An advertiser, person disseminating or processing advertising for MDs and IVDs can be a natural person, a legal person or a natural person-entrepreneur. The law stipulates fines for offences constituting breaches of Act No 40/1995 Coll., on Advertising Regulation in the area of advertising for MDs and IVDs specifically for these persons disseminating, placing or processing advertising for MDs and IVDs.

A natural person acting as a person **disseminating** advertising commits an offence in the area of advertising for MDs and IVDs by:

- Failing to inform a person who evidences legitimate interest who the advertiser or person processing the advertising is.

For this offence, it is possible to impose a fine of up to 500,000,- CZK.

Relevant provisions: Section 8(1)(a) and Section8(5)(b) of Act No 40/1995 Coll., on Advertising Regulation

- Disseminating advertising which is forbidden:

- advertising for goods, services or other performances or values the sale, provision or dissemination of which is in conflict with legal regulations,
- advertising constituting unfair commercial practice pursuant to a special legal regulation,
- advertising disseminated at publicly accessible places outside an outlet in ways other than via advertising or promotional equipment established pursuant to a special legal regulation.

For this offence, it is possible to impose a fine of up to 2,000,000,- CZK.

Relevant provisions: Section 8(1)(b) and Section 8(5)(c) of Act No 40/1995 Coll., on Advertising Regulation

- Breaching the ban on the free deliveries of samples to the general public for an MD or an IVD, which:

- is, according to manufacturer´s instructions, intended solely for use by a healthcare professional,
- may be dispensed only on order or request form issued by the physician pursuant to other legal regulations.

For this offence, it is possible to impose a fine of up to 2,000,000,- CZK.

Relevant provisions: Section 8(1)(d) and Section 8(5)(c) of Act No 40/1995 Coll., on Advertising Regulation

- Disseminating unsolicited advertising in paper form, if harassing for the addressee.

For this offence, it is possible to impose a fine of up to 2,000,000,- CZK.

Relevant provisions: Section 8(1)(h) and Section 8(5)(c) of Act No 40/1995 Coll., on Advertising Regulation

- Disseminating advertising for MDs and IVDs targeted at experts via communication media that are not intended primarily for the experts concerned by the advertising for the product type in question.

For this offence, it is possible to impose a fine of up to 2,000,000,- CZK.

Relevant provisions: Section 8(1)(i) and Section 8(5)(c) of Act No 40/1995 Coll., on Advertising Regulation

- Breaching the ban to offer, promise or provide gifts or other benefits in association with advertising for MDs and IVDs targeted at experts.

For this offence, it is possible to impose a fine of up to 100,000,- CZK.

Relevant provisions: Section 8(1)(j) and Section 8(5)(a) of Act No 40/1995 Coll., on Advertising Regulation

- Failing to provide data about the advertiser or person processing the advertising or person who ordered dissemination of the advertising with it upon request of a surveillance authority within the timeline stipulated thereby.

For this offence, it is possible to impose a fine of up to 500,000,- CZK.

Relevant provisions: Section 8(1)(m) and Section 8(5)(b) of Act No 40/1995 Coll., on Advertising Regulation

A natural person acting as the **advertiser** commits an offence in the area of advertising for MDs and IVDs by:

- Placing advertising that is forbidden:

- advertising for goods, services or other performances or values the sale, provision or dissemination of which is in conflict with legal regulations,
- advertising for a product targeting health, which is not a medicinal product or a medical device or an in vitro diagnostic medical device, suggesting that the product is a medicinal product, medical device or an in vitro diagnostic medical device.

For this offence, it is possible to impose a fine of up to 2,000,000,- CZK.

Relevant provisions: Section 8(2)(a) and Section 8(5)(c) of Act No 40/1995 Coll., on Advertising Regulation

- Breaching the conditions governing the content of advertising for MDs or IVDs or those stipulated by the MDR.

For this offence, it is possible to impose a fine of up to 2,000,000,- CZK.

Relevant provisions: Section 8(2)(b) and Section 8(5)(c) of Act No 40/1995 Coll., on Advertising Regulation

- Breaching the conditions governing comparative advertising which is permissible under the conditions stipulated by Act No 40/1995 and by the Civil Code.

For this offence, it is possible to impose a fine of up to 2,000,000,- CZK.

Relevant provisions: Section 8(2)(c) and Section 8(5)(c) of Act No 40/1995 Coll., on Advertising Regulation

- Failing to keep an example (copy) of each advertising for the minimum period of 5 years of the date it was disseminated. In case an administrative procedure pursuant to Act No 40/1995 Coll. was initiated prior to the expiry of the timeline of 5 years of the date the advertising was disseminated, the advertiser shall be obliged to keep an example (copy) of the advertising that is the subject of the administrative procedure until the final decision in the matter. Or by failing to lend a copy of the advertising to surveillance authorities for the necessary period or by failing to fulfil the obligation to provide, upon request of surveillance authorities, data about the person disseminating and processing the advertising placed by the advertiser and other materials and information concerning this advertising within a predefined timeline for the purposes of an administrative procedure.

For this offence, it is possible to impose a fine of up to 500,000,- CZK.

Relevant provisions: Section 8(2)(d) and Section 8(5)(b) of Act No 40/1995 Coll., on Advertising Regulation

The advertiser is released from responsibility for the content of disseminated advertising which is in conflict with the law, if the advertiser evidences that the person processing the advertising failed to observe the former´s instructions in its processing, due to which the content of the advertising is in conflict with the law. The person processing advertising cannot be released from responsibility for the content of the disseminated advertising by reference to its specification by the advertiser, lest it concerns data the veracity of which the person processing the advertising is not able to assess despite all reasonable efforts.

Relevant provisions: Section 6b(3) of Act No 40/1995 Coll., on Advertising Regulation

A natural person acting as a person **processing** advertising commits an offence in the area of advertising for MDs and IVDs by:

- Processing advertising that is forbidden:

  - advertising for goods, services or other performances or values the sale, provision or dissemination of which is in conflict with legal regulations.

  For this offence, it is possible to impose a fine of up to 2,000,000,- CZK.

Relevant provisions: Section 8(3)(a) and Section 8(5)(c) of Act No 40/1995 Coll., on Advertising Regulation

- Processing advertising constituting an unfair commercial practice.

For this offence, it is possible to impose a fine of up to 2,000,000,- CZK.

Relevant provisions: Section 8(3)(b) and Section8(5)(c) of Act No 40/1995 Coll., on Advertising Regulation

- Breaching the conditions governing comparative advertising that is permissible under conditions stipulated by Act No 40/1995 Coll. and by the Civil Code.

For this offence, it is possible to impose a fine of up to 2,000,000,- CZK.

Relevant provisions: Section 8(3)(c) and Section 8(5)(c) of Act No 40/1995 Coll., on Advertising Regulation

- Breaching the conditions governing the content of advertising for MDs or IVDs or those stipulated by the MDR.

For this offence, it is possible to impose a fine of up to 2,000,000,- CZK.

Relevant provisions: Section 8(3)(d) and Section 8(5(c) of Act No 40/1995 Coll., on Advertising Regulation

- Failing to provide data about the advertiser and person disseminating advertising, if known to it, to the surveillance authority upon request thereof and within the timeline stipulated thereby

For this offence, it is possible to impose a fine of up to 500,000,- CZK.

Relevant provisions: Section 8(3)(f) and Section 8(5)(b) of Act No 40/1995 Coll., on Advertising Regulation

An expert commits and offence by requiring or accepting benefits forbidden by Act No 40/1995 Coll.

- Gifts or other benefits that exceed insignificant value and are not related to the expert activities performed by the expert. By requiring or accepting samples of MDs and IVDs in quantities greater than necessary to try them out and by failing to provide these samples of MDs and IVDs in accordance with their intended purpose and without the provided sample MD or IVD being visibly labelled with the words “Sample not for sale” or “Free sample”
- By requiring or accepting free-of-charge catering, accommodation, and transport during sponsoring of meetings and scientific congresses that are not adequate to the purpose of the meeting, that are not secondary to the purpose of the meeting, and that include persons other than the experts.

For this offence, it is possible to impose a fine of up to 100,000,- CZK.

Relevant provisions: Section 8(4) and Section 8(5)(a) of Act No 40/1995 Coll., on Advertising Regulation

A legal or natural person-entrepreneur acting as a person **disseminating** advertising commits an offence in the area of advertising for MDs and IVDs by:

- Failing to inform a person who evidences legitimate interest who the advertiser or person processing the advertising is

For this offence, it is possible to impose a fine of up to 500,000,- CZK.

Relevant provisions: Section 8a(1)(a) and Section 8a(5)(a) of Act No 40/1995 Coll., on Advertising Regulation

- Disseminating advertising that is forbidden

- advertising for goods, services or other performances or values the sale, provision or dissemination of which is in conflict with legal regulations,
- advertising disseminated at publicly accessible places outside an outlet in ways other than via advertising or promotional equipment established pursuant to a special legal regulation

For this offence, it is possible to impose a fine of up to 2,000,000,- CZK.

Relevant provisions: Section 8a(1)(b) and Section 8a(5)(b) of Act No 40/1995 Coll., on Advertising Regulation

- Disseminating unsolicited advertising in paper form, if harassing for the addressee

For this offence, it is possible to impose a fine of up to 2,000,000,- CZK.

Relevant provisions: Section 8a(1)(c) and Section 8a(5)(b) of Act No 40/1995 Coll., on Advertising Regulation

- Breaching the ban on the free deliveries of samples to the general public for an MD or an IVD, which:

- is, according to manufacturer´s instructions, intended solely for use by a healthcare professional,
- may be dispensed only on order or request form issued by the physician pursuant to other legal regulations.

For this offence, it is possible to impose a fine of up to 2,000,000,- CZK.

Relevant provisions: Section 8a(1)(e) and Section 8a(5)(b) of Act No 40/1995 Coll., on Advertising Regulation

- Disseminating advertising for MDs and IVDs targeted at experts via communication media that are not intended primarily for the experts concerned by the advertising for the product type in question.

For this offence, it is possible to impose a fine of up to 2,000,000,- CZK.

Relevant provisions: Section 8a(1)(f) and Section 8a(5)(b) of Act No 40/1995 Coll., on Advertising Regulation

- Breaching the ban to offer, promise or provide gifts or other benefits in association with advertising for MDs and IVDs targeted at experts.

For this offence, it is possible to impose a fine of up to 2,000,000,- CZK.

Relevant provisions: Section 8a(1)(h) and Section 8a(5)(b) of Act No 40/1995 Coll., on Advertising Regulation

- Disseminating advertising constituting an unfair commercial practice.

For this offence, it is possible to impose a fine of up to 5,000,000,- CZK.

Relevant provisions: Section 8a(1)(n) and Section 8a(5)(c) of Act No 40/1995 Coll., on Advertising Regulation

- Failing to provide data about the advertiser or person processing the advertising or person who ordered dissemination of the advertising with it upon request of a surveillance authority within the timeline stipulated thereby.

For this offence, it is possible to impose a fine of up to 500,000,- CZK.

Relevant provisions: Section 8a(1)(p) and Section 8a(5)(a) of Act No 40/1995 Coll., on Advertising Regulation

A legal or natural person-entrepreneur acting as an **advertiser** commits an offence in the area of advertising for MDs and IVDs by:

- Placing advertising that is forbidden:

• advertising for goods, services or other performances or values the sale, provision or dissemination of which is in conflict with legal regulations,

• advertising for a product targeting health, which is not a medicinal product or a medical device or an in vitro diagnostic medical device, suggesting that the product is a medicinal product, medical device or an in vitro diagnostic medical device.

For this offence, it is possible to impose a fine of up to 2,000,000,- CZK.

Relevant provisions: Section 8a(2)(a) and Section 8a(6)(b) of Act No 40/1995 Coll., on Advertising Regulation

- Placing advertising constituting an unfair commercial practice.

For this offence, it is possible to impose a fine of up to 5,000,000,- CZK.

Relevant provisions: Section 8a(2)(b) and Section 8a(6)(c) of Act No 40/1995 Coll., on Advertising Regulation

- Breaching the conditions governing comparative advertising that is permissible under conditions stipulated by Act No 40/1995 Coll. and by the Civil Code.

For this offence, it is possible to impose a fine of up to 2,000,000,- CZK.

Relevant provisions: Section 8a(2)(c) and Section 8a(6)(b) of Act No 40/1995 Coll., on Advertising Regulation

- Breaching the conditions governing the content of advertising or those stipulated by the MDR.

For this offence, it is possible to impose a fine of up to 2,000,000,- CZK.

Relevant provisions: Section 8a(2)(d) and Section 8a(6)(b) of Act No 40/1995 Coll., on Advertising Regulation

- Failing to keep an example (copy) of each advertising for the minimum period of 5 years of the date it was disseminated. In case an administrative procedure pursuant to Act No 40/1995 Coll. was initiated prior to the expiry of the timeline of 5 years of the date the advertising was disseminated, the advertiser shall be obliged to keep an example (copy) of the advertising that is the subject of the administrative procedure until the final decision in the matter. Or by failing to lend a copy of the advertising to surveillance authorities for the necessary period or by failing to fulfil the obligation to provide, upon request of surveillance authorities, data about the person disseminating and processing the advertising placed by the advertiser and other materials and information concerning this advertising within a predefined timeline for the purposes of an administrative procedure.

For this offence, it is possible to impose a fine of up to 500,000,- CZK.

Relevant provisions: Section 8a(2)(f, g) and Section 8a(6)(a) of Act No 40/1995 Coll., on Advertising Regulation

The advertiser is released from responsibility for the content of disseminated advertising which is in conflict with the law, if the advertiser evidences that the person processing the advertising failed to observe the former´s instructions in its processing, due to which the content of the advertising is in conflict with the law. The person processing advertising cannot be released from responsibility for the content of the disseminated advertising by reference to its specification by the advertiser, lest it concerns data the veracity of which the person processing the advertising is not able to assess despite all reasonable efforts.

Relevant provisions: Section 6b(3) of Act No 40/1995 Coll., on Advertising Regulation

A legal or natural person-entrepreneur acting as a person **processing** advertising commits an offence in the area of advertising for MDs and IVDs by:

- Processing advertising that is forbidden:

- advertising for goods, services or other performances or values the sale, provision or dissemination of which is in conflict with legal regulations

For this offence, it is possible to impose a fine of up to 2,000,000,- CZK.

Relevant provisions: Section 8a(3)(a) and Section 8a(7)(b) of Act No 40/1995 Coll., on Advertising Regulation

- Processing advertising constituting an unfair commercial practice.

For this offence, it is possible to impose a fine of up to 5,000,000,- CZK.

Relevant provisions: Section 8a(3)(b) and Section 8a(7)(c) of Act No 40/1995 Coll., on Advertising Regulation

- Breaching the conditions governing comparative advertising which is permissible under the conditions stipulated by Act No 40/1995 and by the Civil Code.

For this offence, it is possible to impose a fine of up to 2,000,000,- CZK.

Relevant provisions: Section 8a(3)(c) and Section 8a(7)(b) of Act No 40/1995 Coll., on Advertising Regulation

- Breaching the conditions governing the content of advertising or those stipulated by the MDR.

For this offence, it is possible to impose a fine of up to 2,000,000,- CZK.

Relevant provisions: Section 8a(3)(d) and Section 8a(7)(b) of Act No 40/1995 Coll., on Advertising Regulation

- Failing to provide data about the advertiser and person disseminating advertising, if known to it, to the surveillance authority upon request thereof and within the timeline stipulated thereby.

For this offence, it is possible to impose a fine of up to 500,000,- CZK.

Relevant provisions: Section 8a(3)(f) and Section 8a(7)(a) of Act No 40/1995 Coll., on Advertising Regulation

A legal or natural person-entrepreneur commits an offence in the area of advertising for MDs and IVDs by

- Breaching the ban to offer, promise or provide gifts or other benefits in association with advertising for MDs and IVDs targeted at experts, if the aforementioned benefits exceed insignificant value and are not related to the expert activities performed by the expert.
- Providing samples of MDs and IVDs within quantities other than necessary to try them out by experts and not in accordance with their intended purpose and without being visibly labelled with the words “Sample not for sale” or “Free sample”.
- Providing free catering and accommodation and transport during sponsoring of meetings and scientific congresses that are not adequate to the purpose of the meeting, that are not secondary to the purpose of the meeting, and that are extended to persons other than the experts.

For this offence, it is possible to impose a fine of up to 1,000,000,- CZK.

Relevant provisions: Section 8a(4)(a, b) and Section 8a(8)(a) of Act No 40/1995 Coll., on Advertising Regulation

- Requiring or accepting such benefits in association with advertising that are forbidden:
  - Gifts or other benefits in association with advertising for MDs and IVDs targeted at experts.
  - Free catering and accommodation and transport during sponsoring of meetings and scientific congresses that are not adequate to the purpose of the meeting, that are not secondary to the purpose of the meeting, and that are extended to persons other than the experts.

For this offence, it is possible to impose a fine of up to 100,000,- CZK.

Relevant provisions: Section 8a(4)(c) and Section 8a(8)(b) of Act No 40/1995 Coll., on Advertising Regulation