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Information and References Concerning Surveillance over Advertising for Medical Devices and in Vitro Diagnostic Medical Devices

Pursuant to the provision of Section 7(b) of 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"), since 26 May 2021, the State Institute for Drug Control (hereinafter referred to as the "Institute"), has been acting as the authority competent to carry our surveillance over advertising for medical devices (hereinafter referred to as "MD(s)") and in vitro diagnostic medical devices (hereinafter referred to as "IVD(s)") and sponsoring in this area in the Czech Republic, **except for** advertising disseminated via radio and television broadcasting and via on-demand audiovisual 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.

Since 26 May 2021, the Institute has been conducting investigations into instigations concerning potential breaches of effective legal regulations governing advertising for MDs and IVDs, has been issuing expert opinions on advertising activities, materials, and on advertising regulation issues, and has been providing consultations in this area. Furthermore, since 26 May 2021, it has been acting as the authority competent to carry out surveillance over compliance with Article 7 of 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") within scope relevant to advertising for medical devices, and Article 7 of 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") within scope relevant to advertising for in vitro diagnostic medical devices. The law is applicable to advertisers, persons processing or disseminating advertising as well as healthcare experts and employees of healthcare providers, e.g., in those cases where they take part in sponsored or advertising events (meetings of experts and employees of healthcare providers, scientific conferences, congresses, etc.), avail of promotional samples and provide patients with advertising materials about MDs or IVDs.

The points below provide answers and references to the following questions:

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1/ What is the Institute´s role and what are the advertising regulation surveillance authorities?

Prior to 26 May 2021, advertising for MDs and IVDs had not been specifically regulated. Surveillance over compliance with law in case of advertising for MDs and IVDs had been carried out by Regional Trade Licensing Offices consistently with the position of the Ministry of Health and later also of the Institute. Since 26 May 2021, the Institute has been acting as the surveillance authority for MD and IVD advertising and sponsoring in this area, **except for** advertising disseminated via radio and television broadcasting and via on-demand audiovisual media services and video-sharing platform services and for sponsoring in radio and television broadcasting and in on-demand audiovisual media services, and in video-sharing platform services. Furthermore, the Institute has been 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 servicesand for sponsoring in radio and television broadcasting and in on-demand audiovisual media services, and in video-sharing platform servicesconcerning MDs and IVDs is carried out by the Council for Radio and Television Broadcasting – see https://www.rrtv.cz/cz/static/kontakty/index.htm.
Relevant provisions: Section 7(a), (b) of Act No 40/1995 Coll., on Advertising Regulation.

Surveillance over advertising in other industries and fields is carried out by:

- **The Council for Radio and Television Broadcasting (RRTV)** for advertising disseminated via radio and television broadcasting and via on-demand audiovisual 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 https://www.rrtv.cz/cz/static/kontakty/index.htm;
- **The State Institute for Drug Control** for advertising for human medicinal products, human tissues and cells, **except for** *the powers of the RRTV referred to under the point above* https://www.sukl.eu/sukl/contacts;
- **The Ministry of Health**, for advertising for healthcare services and sponsoring in this area, **except for** powers concerning *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* https://www.mzcr.cz/kontakty/;
- **Central Institute for Supervising and Testing in Agriculture,** for advertising for products for the protection of plants and auxiliary products, **except for** powers concerning *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* http://eagri.cz/public/web/ukzuz/kontakty/organizace/;
- **Institute for State Control of Veterinary Biologicals and Medicines,** for advertising for veterinary medicinal products, **except for** powers concerning *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* http://uskvbl.cz/cs/component/content/article/20;

- **Personal Data Protection Office,** for unsolicited advertising disseminated via electronic media pursuant to special legal regulation, where the method of dissemination of such advertising constitutes unfair commercial practice https://www.uoou.cz/vismo/o_utvar.asp?id_u=10**;**
- **Czech Agriculture and Food Inspection Authority,** for requirements stipulated by the Act on Food and Tobacco Products, particularly as concerns the provision of information suggesting that the country of origin of the food is the Czech Republic, for nutritional or health claims pursuant to a directly applicable Regulation of the European Union on nutrition and health claims, for misleading information used contrary to the directly applicable Regulation of the European Union on the provision of information about foods to consumers, and for data used contrary to directly applicable regulations of the European Union stipulating the rules governing the use of designations of origin, geographical indications, and traditional expressions in advertising for foods, including sponsoring, **except for** powers concerning *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* https://www.szpi.gov.cz/clanek/kontakty-pro-verejnost.aspx;
- **Customs offices** for advertising, promotion or support of gambling games forbidden by the Act governing gambling games, and sponsoring in this area, **except for** powers concerning *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*;
- **Regional Trade-Licensing Offices** in other cases – see links to regional trade-licensing offices.

Relevant provisions: *Section 23(10) of Act No 634/1992 Coll., on Consumer Protection;*
Section 24d of Act No 634/1992 Coll., on Consumer Protection;
Section 7 of Act No 40/1995 Coll., on Advertising Regulation;
Section 42 of Act No 500/2004 Coll., the Code of Administrative Procedure.

Links to regional trade-licensing offices:

South Bohemia Region	Krajský úřad – Jihočeský kraj – Odbor Krajský živnostenský úřad Mánesova 3, 37103 České Budějovice http://www.kraj-jihocesky.cz
South Moravia Region	Krajský úřad – Jihomoravský kraj – Odbor Krajský živnostenský úřad, Žerotínovo náměstí 3/5, 60182 Brno http://www.kr-jihomoravsky.cz
Karlovy Vary Region	Krajský úřad – Karlovarský kraj – Krajský živnostenský úřad Závodní 353/88, 36001 Karlovy Vary http://www.kr-karlovarsky.cz
Vysočina Region	Krajský úřad – Kraj Vysočina – Odbor sekretariátu ředitele a krajského živnostenského úřadu Žižkova 57, 58733 Jihlava http://www.kr-vysocina.cz
Hradec Králové Region	Krajský úřad – Královéhradecký kraj Wonkova 1142, 50002 Hradec Králové http://www.kr-kralovehradecky.cz
Liberec Region	Krajský úřad – Liberecký kraj – Odbor krajský živnostenský úřad U Jezu 642/2a, 46180 Liberec 2 http://www.kraj-lbc.cz

Moravian-Silesian Region	Krajský úřad – Moravskoslezský kraj – Krajský živnostenský úřad 28.října 117, 70218 Moravská Ostrava http://www.kr-moravskoslezsky.cz
Olomouc Region	Krajský úřad – Olomoucký kraj – Odbor Krajský živnostenský úřad Jeremenkova 40a, 77900 Olomouc http://www.kr-olomoucky.cz
Pardubice Region	Krajský úřad – Pardubický kraj – Odbor Krajský živnostenský úřad Komenského nám. 125, 53211 Pardubice http://www.pardubickykraj.cz
Pilsen Region	Krajský úřad – Plzeňský kraj – Odbor krajský živnostenský úřad Škroupova 18, 30613 Plzeň http://www.kr-plzensky.cz
Prague	Magistrát hl. města Prahy – Odbor živnostenský Staroměstské nám. 1/4, 11000 Praha 1 http://www.praha.eu
Ústí Region	Krajský úřad – Ústecký kraj – Odbor správních činností a krajský živnostenský úřad Velká Hradební 3118/48, 40002 Ústí nad Labem http://www.kr-ustecky.cz
Zlín Region	Krajský úřad – Zlínský kraj – Odbor Krajský živnostenský úřad Štefánikova ,76190 Zlín http://www.kr-zlinsky.cz

2/ I suspect a potential breach of the Act on Advertising Regulation for MDs and IVDs, what can I do?

Should you suspect a potential breach of the Act on Advertising Regulation for MDs and IVDs, please file an instigation for investigation by the Medical Device Advertising Surveillance Unit (hereinafter referred to also as "DRZP") – see https://www.niszp.cz/cs/kontakt.

Please mark your instigation as "*Instigation for potential breach of Act on Advertising Regulation for MDs and IVDs"*.

Possible methods of submission:

- **in writing** to the following address:
  Sekce regulace zdravotnických prostředků
  Oddělení dozoru nad reklamou zdravotnických prostředků
  Státní ústav pro kontrolu léčiv
  Šrobárova 48
  100 41 Praha 10
- **in person** at the mailroom: https://www.sukl.eu/sukl/mail-room-cash-desk
- **via e-mail to:** drzp@sukl.cz
- **via the data mailbox information system**
  SÚKL data mailbox ID: qwfai2m
  The maximum size of the data message is 20 MB.

For the purposes of investigation into any instigation regarding a breach of the Act on Advertising Regulation for MDs and IVDs, it is advisable to deliver to the Institute the original or copy of the advertising announcement, material, description of or reference to the advertising activity and to specify where and when the advertisement was placed (found or presented).

In case your suspicion of an advertising breach concerns another area, please contact the competent surveillance authority specified under Question no. 1 - What is the Institute´s role and what are the advertising regulation surveillance authorities?

3/ I have a question on Act No 40/1995 Coll., on Advertising Regulation for MDs and IVDs, who should I contact?

In case you have a question on Act No 40/1995 Coll., on Advertising Regulation for MDs and IVDs, please send it to the Advertising Surveillance Unit – see https://www.niszp.cz/cs/kontakt.

Please mark your question as "*Question on MD and IVD advertising*".

Possible methods of submission:

- **in writing** to the following address:
  Sekce regulace zdravotnických prostředků
  Oddělení dozoru nad reklamou zdravotnických prostředků
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- **via e-mail to:** drzp@sukl.cz
- **via the data mailbox information system**
  SÚKL data mailbox ID: qwfai2m
  The maximum size of the data message is 20 MB.

If your question does not concern advertising for MDs and IVDs, and concerns another area, please contact the competent surveillance authority specified under Question no. 1 - What is the Institute´s role and what are the advertising regulation surveillance authorities?

4/ I need a position or opinion on an advertising announcement concerning a MD or an IVD; who should I contact and what should I do?

In case you need a position or opinion on an advertising announcement that concerns MDs and IVDs, please submit an Application for position or opinion on MD and IVD advertising to the Medical Device Advertising Surveillance Unit – see https://www.niszp.cz/cs/kontakt.

Possible methods of submission:

- **in writing** to the following address:
  Sekce regulace zdravotnických prostředků
  Oddělení dozoru nad reklamou zdravotnických prostředků
  Státní ústav pro kontrolu léčiv
  Šrobárova 48
  100 41 Praha 10
- **in person** at the mailroom: https://www.sukl.eu/sukl/mail-room-cash-desk
- **via e-mail to:** drzp@sukl.cz
- **via the data mailbox information system**
  SÚKL data mailbox ID: qwfai2m
  The maximum size of the data message is 20 MB.

If your case does not concern assessment of advertising for MDs and IVDs, but another area, please contact the competent surveillance authority specified under Question no. 1 - What is the Institute´s role and what are the advertising regulation surveillance authorities?

5/ I need a consultation on Act No 40/1995 Coll., on Advertising Regulation concerning MDs and IVDs, who should I contact and what should I do?

If you need a consultation in the area of advertising for MDs and IVDs, please proceed as outlined at https://www.niszp.cz/konzultace.

6/ I have received a call regarding suspected breach of Act No 40/1995 Coll., on Advertising Regulation, concerning MDs and IVDs, but I am not able to send all of the required information within the set timeline. Who should I contact and what should I do?

In case you know that you will not manage to send all of the required information mentioned by the call to the Institute within the set timeline, **prior to the expiry of the timeline defined by the call,** you can ask the Institute to extend the timeline. The request for timeline extension must contain particulars set forth by Section 37 of the Code of Administrative Procedure, which stipulates: "*A submission must clearly show who has filed it, in respect of what case and what is being proposed. A natural person shall specify the name, surname, date of birth, and place of permanent residence or other mailing address referred to under Section 19(3), if applicable, in the submission. In submissions pertaining to the person´s business activities, the natural person shall specify name and surname, and/or the complement distinguishing the person of the entrepreneur or the type of business associated with this person or the type of business carried out thereby, the identification number of the person and the address entered in the Companies Register or another register stipulated by law as the place of business or another mailing address, if applicable. A legal person shall specify its name or company name, identification number of the person or a similar detail and the address of the registered office, or another mailing address, if applicable, in the submission. The submission shall contain the identification of the administrative authority to which it is addressed, other particulars stipulated by law, and a signature of the person making the submission.*"
The request for timeline extension must contain an adequate reason for which it is not possible to send the required information to the Institute within the timeline. Furthermore, it is advisable to suggest a reasonable period by which you request that the timeline be extended.

Possible methods of submission:

- **in writing** to the following address:
  Sekce regulace zdravotnických prostředků
  Oddělení dozoru nad reklamou zdravotnických prostředků
  Státní ústav pro kontrolu léčiv
  Šrobárova 48
  100 41 Praha 10
- **in person** at the mailroom: https://www.sukl.eu/sukl/mail-room-cash-desk
- **via e-mail to:** drzp@sukl.cz
- **via the data mailbox information system**
  SÚKL data mailbox ID: qwfai2m
  The maximum size of the data message is 20 MB.

7/ I have received a call regarding suspected breach of Act No 40/1995 Coll., on Advertising Regulation concerning MDs and IVDs, and I would like to be represented on the basis of a Power of Attorney. Where can I find the information?

General information concerning the submission of powers of attorney, including the mandatory data for individual types of powers of attorney, methods of certification and sending of powers of attorney and mailing information is available from https://www.sukl.eu/sukl/example-letter-of-authorisation.