UST-41 version 1 Provision of Promotional Samples of Medical Devices and in Vitro Diagnostic Medical Devices

This Guideline supersedes Guideline UST-41 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 95/2004 Coll., on Requirements for Acquisition and Recognition of Expert Competence and Specialised Competence to Practise the Profession of a Physician, Dentist and Pharmacist, as amended (hereinafter referred to as "Act No 95/2004 Coll.")
- Act No 96/2004 Coll., on Requirements for Acquisition and Recognition of Competence for Pursuing Non-Medical Healthcare Professions and Activities Associated with the Provision of Health Care and on Amendment to Some Related Acts, as amended (hereinafter referred to as "Act No 96/2004 Coll., on Non-Medical Healthcare Professions")
- Act No 372/2011 Coll., on Healthcare Services and the Conditions of Their Provision (Act on Healthcare Services), as amended (hereinafter referred to as "Act No 372/2011 Coll., on Healthcare Services")
- 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)") and provides greater detail to the information presented in Guideline UST-39 Regulation of Advertising for Medical Devices and in Vitro Diagnostic Medical Devices concerning the provision of promotional samples of MDs and IVDs as referred to under Act No 40/1995 Coll., on Advertising Regulation, falling within the powers of the State Institute for Drug Control (hereinafter referred to as the "Institute"). The Guideline is of recommendatory nature.

Pursuant to the provision of Section 5k(1)(b), Section 5l(2), and Section 5m(2) of Act No 40/1995 Coll., on Advertising Regulation, the provision of samples of MDs and IVDs is deemed to be advertising.

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I. Provision of promotional samples of MDs and IVDs to the general public:

The provision of Section 5l(2) of Act No 40/1995 Coll., on Advertising Regulation stipulates: "*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, is forbidden. The provision of samples of such MDs or IVDs to the general public that may be dispensed only on order or request form issued by the physician is forbidden."*

Another requirement set forth by the provision of Section 5k(3) of **Act No** 40/1995 Coll., on Advertising Regulation reads: "*The subject of advertising may only be a medical device that may be placed on the market in compliance with the MDR or an in vitro diagnostic medical device that may be placed on the market in compliance with the IVDR, unless stipulated otherwise below."*

Furthermore, Article 25 of the MDR (and analogously for IVDs, Article 22 of the IVDR) stipulates identification within the supply chain, specifically: "***Distributors and importers*** *shall co-operate with manufacturers or authorised representatives* ***to achieve an appropriate level of traceability of devices****. Economic operators shall be able to identify the following to the competent authority, for the period referred to in Article 10(8):*

a) any economic operator to whom they have directly supplied a device;
b) any economic operator who has directly supplied them with a device;
c) any health institution or healthcare professional to which they have directly supplied a device."

Furthermore, Art. 10(8) of the MDR (and analogously for IVDs, the same article of the IVDR) stipulates that: "***Manufacturers*** *shall keep the technical documentation, the EU declaration of conformity and, if applicable, a copy of any relevant certificate, including any amendments and supplements, issued in accordance with Article 56, available for the competent authorities for a period of at least 10 years after the last device covered by the EU declaration of conformity has been placed on the market. In the case of implantable devices, the period shall be at least 15 years after the last device has been placed on the market.*

Upon request by a competent authority, the manufacturer shall, as indicated therein, provide that technical documentation in its entirety or a summary thereof.

A manufacturer with a registered place of business outside the Union shall, in order to allow its authorised representative to fulfil the tasks mentioned in Article 11(3), ensure that the authorised representative has the necessary documentation permanently available."

Furthermore, Article 83 of the MDR (and analogously for IVDs, Article 78 of the IVDR) stipulates that: *"For each device,* ***manufacturers*** *shall plan, establish, document, implement, maintain and update a* ***post-market surveillance system*** *in a manner that is proportionate to the risk class and appropriate for the type of device. That system shall be an integral part of the manufacturer's quality management system referred to in Article 10(9).*

2. The post-market surveillance system shall be suited to actively and systematically gathering, recording and analysing relevant data on the quality, performance and safety of a device throughout its entire lifetime, and ***to drawing the necessary conclusions and to determining, implementing and monitoring any preventive and corrective actions****.*

3. Data gathered by the manufacturer's post-market surveillance system shall in particular be used:

a) to update the benefit-risk determination and to improve the risk management as referred to in Chapter I of Annex I;
b) to update the design and manufacturing information, the instructions for use and the labelling;
c) to update the clinical evaluation;
d) to update the summary of safety and clinical performance referred to in Article 32;
e) for the identification of needs for preventive, corrective or field safety corrective action;
f) for the identification of options to improve the usability, performance and safety of the device;
g) when relevant, to contribute to the post-market surveillance of other devices; and
h) to detect and report trends in accordance with Article 88.

The technical documentation shall be updated accordingly.

4. If, in the course of the post-market surveillance, a need for preventive or corrective action or both is identified, the manufacturer shall implement the appropriate measures and inform the competent authorities concerned and, where applicable, the notified body. Where a serious incident is identified or a field safety corrective action is implemented, it shall be reported in accordance with Article 87."

Furthermore, Article 84 of the MDR (and analogously for IVDs, Article 79 of the IVDR) mentions the Post-market surveillance plan, stipulating the following: "*The post-market surveillance system referred to in Article 83 shall be based on a post-market surveillance plan, the requirements for which are set out in Section 1.1 of Annex III. For devices other than custom-made devices, the post-market surveillance plan shall be part of the technical documentation specified in Annex II."*

Furthermore, Article 85 of the MDR (and analogously for IVDs, Article 80 of the IVDR) refers to the Post-market surveillance report as follows: "*Manufacturers of class I devices shall prepare a post-market surveillance report summarising the results and conclusions of the analyses of the post-market surveillance data gathered as a result of the post-market surveillance plan referred to in Article 84 together with a rationale and description of any preventive and corrective actions taken. The report shall be updated when necessary and made available to the competent authority upon request."*

Furthermore, Article 86 of the MDR (and analogously for IVDs, Article 81 of the IVDR) refers to the Periodic Safety Update Report, stipulating the following: "*Manufacturers of class IIa, class IIb and class III devices shall prepare a periodic safety update report ('PSUR') for each device and where relevant for each category or group of devices summarising the results and conclusions of the analyses of the post-market surveillance data gathered as a result of the post-market surveillance plan referred to in Article 84 together with a rationale and description of any preventive and corrective actions taken. Throughout the lifetime of the device concerned, that PSUR shall set out:*

- *a) the conclusions of the benefit-risk determination;*
- *b) the main findings of the PMCF; and*
- *c)* ***the volume of sales of the device and an estimate evaluation of the size and other characteristics of the population using the device*** *and, where practicable, the usage frequency of the device.*

Manufacturers of class IIb and class III devices shall update *the PSUR* ***at least annually****. That PSUR shall, except in the case of custom-made devices, be part of the technical documentation as specified in Annexes II and III.*

Manufacturers of class IIa devices *shall* ***update*** *the PSUR* ***when necessary and at least every two years****. That PSUR shall, except in the case of custom-made devices, be part of the technical documentation as specified in Annexes II and III.*

For custom-made devices, the PSUR shall be part of the documentation referred to in Section 2 of Annex XIII.

2. For ***class III devices or implantable devices, manufacturers shall submit PSURs*** *by means of the electronic system referred to in Article 92* ***to the notified body*** *involved in the conformity assessment in accordance with Article 52. The notified body shall review the report and add its evaluation to that electronic system with details of any action taken. Such PSURs and the evaluation by the notified body shall be made available to competent authorities through that electronic system.*

3. For devices other than those referred to in paragraph 2, manufacturers shall make PSURs available to the notified body involved in the conformity assessment and, upon request, to competent authorities."

Annex III to the MDR (and analogously for IVDs, the same Annex to the IVDR) stipulates the requirements for technical documentation on post-market surveillance, specifically:

"*The technical documentation on post-market surveillance to be drawn up by the manufacturer in accordance with Articles 83 to 86 shall be presented in a clear, organised, readily searchable and unambiguous manner and shall include in particular the elements described in this Annex.*

1.1. The post-market surveillance plan drawn up in accordance with Article 84.

The manufacturer shall prove in a post-market surveillance plan that it complies with the obligation referred to in Article 83.

- *a) The post-market surveillance plan shall address the collection and utilization of available information, in particular:*

- information concerning serious incidents, including information from PSURs, and field safety corrective actions;

- records referring to non-serious incidents and data on any undesirable side-effects;

- information from trend reporting;

- relevant specialist or technical literature, databases and/or registers;

*- **information, including feedbacks and complaints, provided by users, distributors and importers; and***

- publicly available information about similar medical devices.

b) The post-market surveillance plan shall cover at least:

- a proactive and systematic process to collect any information referred to in point (a). The process shall allow a correct characterisation of the performance of the devices and shall also allow a comparison to be made between the device and similar products available on the market;

- effective and appropriate methods and processes to assess the collected data;

- suitable indicators and threshold values that shall be used in the continuous reassessment of the benefit-risk analysis and of the risk management as referred to in Section 3 of Annex I;

- effective and appropriate methods and tools to investigate complaints and analyse market-related experience collected in the field;

- methods and protocols to manage the events subject to the trend report as provided for in Article 88, including the methods and protocols to be used to establish any statistically significant increase in the frequency or severity of incidents as well as the observation period;

- methods and protocols to communicate effectively with competent authorities, notified bodies, economic operators and users;

- reference to procedures to fulfil the manufacturers obligations laid down in Articles 83, 84 and 86;

- systematic procedures to identify and initiate appropriate measures including corrective actions;

*- **effective tools to trace and identify devices for which corrective actions might be necessary**; and*

- a PMCF plan as referred to in Part B of Annex XIV, or a justification as to why a PMCF is not applicable.

1.2. The PSUR referred to in Article 86 and the post-market surveillance report referred to in Article 85."

Annex 3(6) of Government Regulation No 56/2015 Coll. lays down the post-market obligations as follows: "*1. The manufacturer shall establish and keep an updated systematic procedure for the evaluation of experience obtained from an in vitro diagnostic medical device placed on the market, including performance evaluation in compliance with the Act on Medical Devices. This obligation of the manufacturer includes the obligation to report to the Institute incidents as referred to under the Act on Medical Devices, and such reporting must be done forthwith, no later, however, than within 15 days of learning of the incident.*

2. The manufacturer shall adopt adequate measures allowing to implement any necessary corrective action with a view to the nature and risks associated with the in vitro diagnostic medical device."

The aforementioned implies that it is forbidden to provide to the general public samples of such MDs and IVDs, in respect of which the manufacturer in their instructions specifies that they are intended solely for use by healthcare professionals, or of such MDs and IVDs that may be dispensed solely on order or request form issued by a physician. Except for the aforementioned MDs and IVDs, Act No 40/1995 Coll., on Advertising Regulation does not set forth any other requirement for the provision of samples to the general public; therefore, it is possible to provide to the general public samples of MDs and IVDs that meet the requirements for the placement of the MDs and IVDs on the market pursuant to effective legislation governing MDs and IVDs. Act No 40/1995 Coll., on Advertising Regulation, does not stipulate any quantity limit for the provision of samples to the general public, either. The condition for the provision of promotional samples of MDs and IVDs to the general public is that a promotional sample provided in this manner must comply with the requirements laid down by effective legislation for the placement on the market and must be provided in compliance with the expiry date of the MD or IVD set by the manufacturer. Also, if the manufacturer has issued Instructions for Use of the MD or IVD, it must be also attached to the provided promotional samples of the MD or IVD and the general public must be properly advised in compliance with the manufacturer´s

instructions. Moreover, the general public must be advised about who should be contacted in case unusual problems with the sample MD or IVD provided in this manner arise and what data is needed for potential investigation if an incident or suspected incident of the provided MD or IVD promotional sample is to be reported.

Are there any requirements governing the record-keeping and distribution of MD and IVD promotional samples provided to the general public?

Pursuant to the provision of Section 5l of Act No 40/1995 Coll., on Advertising Regulation, unlike for medicinal products, there are no requirements laid down for the reporting of the number of deliveries of distributed MDs and IVDs and of provided samples of MDs and IVDs to the Institute. Article 25 of the MDR and Article 22 of the IVDR stipulates identification within the supply chain – see the obligations of distributors, importers, and manufacturers above. From the perspective of distribution practice, there are no limitations or benefits arising from the fact that the item is an MD or IVD promotional sample. Therefore, it is necessary to comply with the rules governing the handling of devices as set forth by the relevant legislation. The provision of free MD and IVD samples also meets the definition of distribution as stipulated by the MDR, and for this reason, it is necessary to observe all of its requirements, i.e., if a device is not distributed in the packaging provided by the manufacturer, the entity who carries out repackaging must proceed as outlined in Article 16 of the MDR.

II. Provision of promotional samples of MDs and IVDs to <u>experts</u>:

Section 5m(2) of Act No 40/1995 Coll., on Advertising Regulation stipulates: "*In association with advertising for medical devices and in vitro diagnostic medical devices targeted at experts, it is forbidden to offer, promise or provide gifts or other benefits to the experts, unless these are of insignificant value and related to the expert activity performed by the expert. This shall not apply to the provision of samples of medical devices and in vitro diagnostic medical devices* ***in quantities necessary to try out the medial device and in vitro diagnostic medical device in accordance with its intended purpose.*** *The sample medical device or in vitro diagnostic medical device provided in this manner* ***must be visibly labelled with the words "Sample not for sale" or "Free sample".***"

The aforementioned implies that experts can be provided with promotional MD and IVD samples in quantities necessary to try them out in accordance with their intended purpose. Promotional samples of MDs and IVDs provided to experts must be visibly labelled with the words ***"Sample not for sale" or "Free sample"***. Promotional samples of MDs and IVDs hence cannot be provided to experts in return for payment (not even for the price established by the manufacturer or a lower price). The condition governing the provision of promotional samples of MDs and IVDs to experts is that even a promotional sample provided in this manner must meet the requirements of effective legislation for placement on the market and it must be provided in accordance with the expiry date of the MD or IVD set by the manufacturer. Furthermore, if the manufacturer has issued instructions for use of the MD or IVD, it must be also attached to the provided MD or IVD promotional sample and the sales representative must provide the expert with all of the necessary information, including information on whether the MD or IVD may be dispensed only on order or request form issued by a physician pursuant to other legal regulations and whether the MD or IVD is an MD or IVD fully or partially reimbursed from public health insurance. Should the provision of samples of MDs or IVDs reimbursed fully or partially from the public health insurance assume the form of a consumer competition based upon the quantities of prescribed, dispensed or used devices, the provision of MD or IVD samples to the expert as referred to under the provision of Section 5k(7) of Act No 40/1995 Coll., on Advertising Regulation, is forbidden.

List of MDs dispensed only on order as per the provision of Section 8 of Decree No 377/2022 Coll., implementing some provisions of the Act on Medical Devices – List of groups of medical devices that may jeopardise the lives or health of people

a) intrauterine devices;
b) devices to treat breathing disorders in sleep;
c) implantable devices applied by injection;
d) hearing aids; and
e) contact lenses if used in children under the age of 15 years.

How are the quantities of promotional samples necessary for the expert to try the MD or IVD out defined?

With regard to the fact that experts may be provided with MD and IVD samples in quantities allowing the expert to try them out **in accordance with the intended purpose,** i.e., in the treatment of a patient in accordance with the intended purpose of the MD or IVD defined by the manufacturer, from the perspective of the Institute, due to the division into risk classes and lists of IVDs, it is not possible to define a uniform limit for the number of promotional samples for a single expert that would be applicable to all MDs, and for this reason, the corresponding amount of MD and IVD promotional samples will be assessed case by case.

Also, the quantity necessary for the expert to try the promotional samples out is based on the potential number of patients with the specific disease who are in care of the respective expert and for whom the use of the MD or IVD is intended. The use of a provided MD or IVD promotional sample within the scope of the health care provided by the expert must be recorded by the expert in the patient´s medical records for the purposes of potential incidents and, at the time of follow-up, the expert should evaluate the performance of the MD or IVD used by the expert in the patient as a promotional sample – for more details, please refer to Annex 1 hereto.

Are there any requirements governing the record-keeping and distribution of MD and IVD promotional samples provided to experts?

Pursuant to the provision of Section 5m of Act No 40/1995 Coll., on Advertising Regulation, unlike for medicinal products, there are no requirements for the reporting of the number of deliveries of distributed MDs and IVDs and of provided samples of MDs and IVDs to the Institute. Article 25 of the MDR lays down the identification within the supply chain – please refer above for the obligations of distributors, importers, and manufacturers. With a view to the aforementioned, the Institute recommends to keep records of the provided MD and IVD promotional samples, with documentation of the provided MD or IVD sample take-over by the expert, specifying the number, trade name of the MD and IVD and the MD and IVD batch number, if specified by the manufacturer, as part of the post-market surveillance system for MDs and IVDs.

The provision of Section 53(2)(d) of Act No 372/2011 Coll., on Healthcare Services stipulates: "*Medical records, with a view to the purpose of the field they pertain to, shall contain information about the patient´s condition of health, about the course and outcome of the provided healthcare services, and about other significant circumstances associated with the patient´s condition of health and with the course of action taken in the provision of healthcare services*". On the basis of the aforementioned, in the provision of healthcare services, the expert should document in the patient´s medical records that in the provision of healthcare services, an MD or IVD promotional sample was used in the patient as suitable for the patient's condition of health and in accordance with the MD or IVD intended purpose. Furthermore, the expert should thereafter evaluate the outcome of the use of the sample MD or IVD, specifying the effect on the patient, and enter the outcome in the medical records in compliance with the requirements set forth by Act No 372/2011 Coll., on Healthcare Services. Should an incident with the provided sample MD or IVD occur, the expert must evidence and submit the documentation of the provided samples of MDs and IVDs used in the patient for the purposes of potential investigation pursuant to the provision of Part Nine of TITLE I of Act No 375/2022 Coll. and Sections 2 of the MDR and the IVDR. Furthermore, the provisions of Section 39 and Section 40 of Act No 375/2022 Coll. stipulate the requirements governing the obligations of healthcare service providers in the use of a device – Annex 1 hereto refers.

III. Handling of MD and IVD samples

Any person handling promotional samples of MDs and IVDs (distributors, sales representatives, persons authorised to prescribe and dispense MDs and IVDs) may handle samples only if meeting the conditions stipulated not only by the Act on Advertising Regulation, but also effective legislation governing MDs and IVDs. It is necessary to safeguard adequate storage conditions, expiry, integrity of packaging, etc.

Annex 1: Obligations of Healthcare Providers in the Use of Devices

Section 39 of Act No 375/2022 Coll.

(1) The healthcare provider shall be obliged to ensure that

a) **the device is used in compliance with the manufacturer's instructions;**

b) **a device with measuring function is operated in compliance with the requirements stipulated by another legal regulation governing the sphere of metrology;**

c) **the person providing healthcare services is instructed about the necessity to make sure, prior to each use of the device, that the device is in proper technical condition, functional, and may be safely used, where such device check is practicable; this requirement shall adequately apply also to the accessories, software, and another product which is expected to interact with the device in question;**

d) **good storage practice is observed;**

e) the device is serviced in compliance herewith;

f) in case the manufacturer provided the healthcare provider with a custom-made medical device for use in the provision of healthcare services for a specific patient, the healthcare provider provided this patient with the manufacturer's statement for the custom-made medical device referred to under Annex XIII(1) of the Medical Device Regulation, which was attached by the manufacturer to this medical device; and

g) **a field safety corrective action determined by the manufacturer in order to eliminate or mitigate the risks of a serious incident associated with the device supplied onto the market has been implemented**.

(2) The healthcare provider must not use the device in the provision of healthcare services where cases listed under Section 38(1) are concerned. Furthermore, the healthcare provider must not use the device in the provision of healthcare services in case the instructions for use in the Czech language are not available thereto; this shall not apply to risk class I or IIa medical devices or to those in vitro diagnostic medical devices for which the manufacturer determined that the safe use of the device does not require instructions for use.

(3) **Where a risk class IIb or III medical device is used in the provision of healthcare services, the healthcare provider shall be obliged to make a record of such use in the medical documentation kept for the patient.**

(4) **The healthcare provider shall be obliged to keep unique identification of devices, except for risk class I medical devices and risk class A in vitro diagnostic medical devices supplied thereto. Healthcare providers shall be obliged to present this information to the Institute upon request of the latter**.

(5) **The healthcare provider shall be obliged to keep documentation of the used devices**

a) for which training must be conducted;

b) for which a safety technical control must be carried out; or

c) which have been determined to be legal working measuring instruments by a legal regulation governing the sphere of metrology.

(6) **The content of the documentation of used devices referred to under paragraph (5) is stipulated by an implementing legal regulation.**

Section 40 of Act No 375/2022 Coll.

Device information

(1) The healthcare provider shall be obliged to ensure that the complete information from the instructions for use in the Czech language is available to the person providing healthcare services by means of the device; the obligation to arrange for the availability of the instructions for use shall not apply to risk class I or IIa medical devices or to in vitro diagnostic medical devices in respect of which the manufacturer determined that the safe use of the device does not require such instructions for use.

(2) The healthcare provider who has implanted an implantable device shall be obliged to provably provide the patient who has been implanted this medical device or his/her legal guardian or carer with the implant card that shall specify the identity of the patient and information referred to under Article 18 of the Medical

Device Regulation in any provable manner that will allow the patient ready access to the concerned information. The information must be in the Czech language.

(3) The obligation stipulated by paragraph (2) shall not apply to medical devices referred to under Art. 18(3) of the Medical Device Regulation stipulating: "*The following implants shall be exempted from the obligations laid down in this Article: sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors. The Commission is empowered to adopt delegated acts in accordance with Article 115 to amend this list by adding other types of implants to it or by removing implants therefrom.*"