62/2015 Coll.

DECREE

of 31 March 2015

implementing certain provisions of the Act on Medical Devices

In compliance with Section 96, paragraph 2 of Act No 268/2014 Coll. on Medical Devices and on Amendment to Act No 634/2004 Coll., on Administrative Fees, as amended (hereinafter referred to as the Act), the Ministry of Health, implementing Section 6, paragraph 2, Section 19, paragraph 2, letter n), Section 45, paragraph 2, Section 46, paragraph 2, Section 48, paragraph 3, Section 56, paragraph 2, letter a), Section 59, paragraph 4, Section 71, paragraph 6 a Section 74, paragraph 5 of the Act, hereby stipulates:

Section 1

Subject-matter

This Decree lays down

a) particulars of serious adverse incident reporting prior to the placement of a medical device on the market;
b) rules of good import and distribution practice;
c) a list of medical devices which may jeopardise the life or health of humans;
d) particulars of an order;
e) a list of medical devices the use and handling of which is generally known;
f) particulars of medical device documentation;
g) procedures in reporting suspected adverse incidents, adverse incidents, field safety corrective actions, and safety alerts; and
h) generic groups of medical devices.

Section 2

Particulars of serious adverse incident reporting prior to the placement of a medical device on the market

[Implementing Section 19, paragraph 2, letter n) of the Act]

(1) A serious adverse incident reporting shall contain the following particulars:

a) title of the medical device clinical investigation and protocol number;
b) identification number of the clinical trial allocated by the European databank of medical devices Eudamed;
c) data about the contact person, specifically the name and address of his/her residence, where a natural person is concerned, and the name or business name and address of its registered office where a legal person is concerned, furthermore, e-mail and telephone number for both;
d) name of the investigational medical device;
e) the number of subjects enrolled in the clinical investigation as of the date of the serious adverse incident reporting;
f) date of receipt of the serious adverse incident report by the sponsor of the clinical investigation;
g) date of occurrence, if known, and a description of the serious adverse incident;
h) date of use of the investigational medical device, during which the adverse incident occurred;
i) personal identification number allocated to the trial subject;
j) information on the consequence of the adverse incident;
k) information on adopted measures;
l) supplementation with new findings from the evaluation of the serious adverse incident; and
m) conclusion from the evaluation of the serious adverse incident.

(2) Serious adverse incident reporting shall be done using the serious adverse incident report form as referred to by the European Commission's guidance for serious adverse incident reporting. On its website, the Institute shall publish a Czech and English versions of the serious adverse incident report form.

(3) A sponsor of clinical investigation shall report to the Institute serious adverse incidents via the electronically completed serious adverse incident report form signed with a certified electronic signature in the Czech or English language.

Section 3

Performance of distribution and import activities

(Implementing Section 45, paragraph 2 of the Act)

(1) A distributor and importer shall safeguard the transportation of a medical device in a manner allowing to observe

the transport conditions determined by the manufacturer. To prevent its contamination, damage, theft, corruption or confusion, a medical device must not be exposed to adverse influences. Responsibility for the safeguarding of conditions shall be borne by the distributor and importer also in cases where transportation is executed via third parties.

(2) Where the transportation of a medical device is safeguarded by the dispensing person, seller or provider of healthcare services, conditions of transportation set forth by paragraph 1 must be met.

(3) A distributor, importer, dispensing person, seller and provider of healthcare services shall store the medical device in a manner allowing

a) to maintain the storage conditions determined by the manufacturer;
b) a medical device past its expiry, if established by the manufacturer, to be stored separately at an indicated location and not to be further distributed;
c) a medical device with compromised original packaging, which resulted in deterioration of the medical device characteristics or performance, or a medical device which is suspected to be contaminated, to be stored separately at an indicated location and not to be further distributed;
d) a medical device withdrawn from the market and recalled upon suspected adverse incident or due to an adverse incident, to be located separately at an indicated location and not to be further distributed;
e) to prevent contamination, damage, theft, corruption of medical devices and confusion between them; and
f) a medical device under complaints procedure to be located separately at an identified location.

(4) Documentation of receipted, supplied medical device or medical device removed from storage shall contain

a) identification of the medical device by means of specifying the manufacturing batch number preceded with the symbol “LOT” or the serial number, if specified by the manufacturer;
b) the date by which it is possible to safely use the medical device, if determined by the manufacturer;
c) the quantity or number of receipted medical device, supplied medical device or medical device removed from storage; and
d) the identification of the clients.

(5) The documentation maintained and stored by the distributor and importer which is pertaining to the process of withdrawing a medical device from the market and the process of recalling a medical device upon suspected adverse incident or due to an adverse incident, shall contain

a) the definition of personal and material responsibility for the conduct and coordination of withdrawal/recall;
b) written records about communication among persons responsible for the process of medical device withdrawal/recall;
c) records on the medical device withdrawal/recall procedure;
d) identification of all clients;
e) records on withdrawal/recall related activities; and
f) a withdrawal/recall evaluation and measures implemented in cases where withdrawal/recall is not practicable.

(6) The documentation referred to by paragraphs 4 and 5 shall be stored for the period of five years.

Section 4

Premises and technical equipment

(Implementing Section 45, paragraph 2 of the Act)

(1) A distributor, importer, and, where applicable with a view to their needs, the dispensing person, seller and provider of healthcare services shall safeguard the premises for the activities of distribution and import of a medical device in a manner preventing any damage and contamination of the medical device.

(2) A distributor, importer, and, where applicable with a view to their needs, the dispensing person, seller and provider of healthcare services shall safeguard dry and clean premises for the storage of medical devices which shall meet

a) temperature requirements where the manufacturer has determined a specific temperature range for the storage of the medical device; and shall safeguard temperature measurements and record-keeping of at least the daily maximums and minimums of these measurements; the records of these measurements shall be stored for the period of five years thereby;
b) other specific storage conditions with a view to the risks class of the medical device if determined by the manufacturer;
c) effective measures preventing the penetration of insects, animals, dust, fungi, and other contamination of the medical device; and
d) resistance of floors and shelf surfaces against disinfectants.

(3) A distributor and importer shall safeguard premises to meet the hygienic needs of the employees and for the conduct of cleaning; these premises shall be separated from storage premises. The premises for a dayroom and place for the preparation and consumption of food must be separated from the premises for distribution and import activities.

(4) A distributor, importer, and, where applicable with a view to their needs, the dispensing person and seller shall observe the procedures governing the method of regular cleaning, tidying, disinfection, and maintenance of hygiene within the premises dedicated to the activities of distribution and import and to the operation of employees in these premises. Compliance with these procedures shall be regularly checked and recorded. Records on conducted checks shall be visibly located within the respective premises. These records shall be stored for the period of one year.

Section 5

Controls and corrective actions

(Implementing Section 45, paragraph 2 of the Act)

(1) A distributor and importer shall implement and document the internal process control system for distribution and import activities, shall adopt corrective actions on the basis of outputs from internal controls, which are conducted at least once a year, and shall keep records of complaints procedures and results thereof.

(2) Where necessary and with a view to the nature of the medical device, a distributor and importer shall draw and regularly update written procedures for receipt activities, controls of deliveries, storage, premise cleaning and maintenance, controls of storage conditions, including the protection of the medical device during storage and transportation, ordering, supplying, including transportation by clients and complaints procedures.

(3) Records referred to in paragraphs 1 and 2 shall be stored for the period of five years.

Section 6

List of groups of medical devices which may jeopardise the life or health of humans

(Implementing Section 46, paragraph 2 of the Act)

Groups of medical devices which, even if their intended purpose is observed, may jeopardise the health or life of humans if used without medical supervision and which are dispensed upon order only, shall be

a) intrauterine devices;
b) medical devices for the treatment of sleep breathing disorders;
c) high-performance inhalers;
d) respiratory medical devices;
e) medical devices for long-term home oxygenotherapy;
f) contact lenses for children and adolescents up to 15 years of age;
g) implantable medical devices which are applied by injection; and
h) hearing aids.

Section 7

Particulars of an order

(Implementing Section 48, paragraph 3 of the Act)

(1) The following data shall be specified on the order:

a) identification of the health insurance company by a numeric code;
b) patient's name, patient's contact address, patient's telephone number if the patient agrees with it; insured person's number, if allocated; date of birth where the insured person's number was not allocated; in case of the Prison Service of the Czech Republic, the name and address of the detention prison facility for a patient accused of a crime, the name and address of the prison facility for a patient sentenced for a crime, and the name of the prison facility for a patient confined in a security detention shall be specified; in case of an order issued upon request of a patient who intends to use the order in another Member State the date of birth shall be always specified in addition to the aforementioned data[1)];
c) the prescribed medical device, specifically its trade name, under which the medical device is placed on the market, the name supplement identifying the medical device variant, where it exists, the code under which the medical device is registered by the concerned health insurance company, and the number of packages where a serially manufactured medical device is concerned;
d) the individually proposed characteristics of the medical device and the code under which the medical device is registered by the concerned health insurance where a custom-made medical device is concerned;
e) the patient's diagnosis for which the medical device is prescribed to the patient; the diagnosis shall be specified by means of a code of the International Classification of Diseases;
f) the words "To be paid by the patient" where a medical device which is not reimbursed from the public health insurance is concerned,
g) a stamp of the provider of healthcare services containing[1)],
1. the name of the provider of healthcare services, address of the site of healthcare service provision, identifier of the healthcare facility workplace, if allocated by the health insurance company, and telephone number where a natural person is concerned, or
2. the name or business name, registered office, the site of healthcare service provision, identifier of the healthcare facility workplace, if allocated by the health insurance company, and telephone number where a legal person is concerned;

h) the name of the prescribing doctor written out in print or as a name tag, and, furthermore, where an order issued upon request of a patient who intends to use it in another Member State is concerned, the expert qualification and contact details of the prescribing doctor, specifically e-mail and telephone or fax with the international prefix, and the words "Czech Republic" shall be specified[1)];

i) signature of the prescribing doctor;[1)] and

j) the order issue date[1)].

(2) Where the reimbursement of a medical device is conditioned by approval of the review doctor of the concerned health insurance company, the review doctor shall

a) put the words “Approved by review doctor”, the date of approval, and signature on the front side of the order and shall stamp it with his/her stamp; or
b) issue a written approval of repeated prescribing of medical devices; the written approval shall be filed in the patient's medical documentation no later than within 14 days of its issue; the prescribing doctor shall put the words “Approved by review doctor” on the front side of the order issued on the basis of the written approval of the review doctor.

(3) Where a medical device the reimbursement of which is conditioned by the approval of a review doctor of the concerned health insurance company is concerned and the prescribing doctor is a doctor of the Prison Service of the Czech Republic, the medical device order shall be sent to the review doctor of the concerned health insurance company for endorsement by this doctor. Otherwise, procedure outlined in paragraph 2, letter b) shall be followed.

(4) In case of prescribing a medical device which may directly or indirectly jeopardise the health of humans and which is not reimbursed from the public health insurance system, the order shall bear the particulars referred to in paragraph 1 except for letter a).

Section 8

Particulars of a medical device order issued in another Member State of the European Union

(Implementing Section 48, paragraph 3 of the Act)

The particulars of a medical device order set forth hereby shall not be required where an order issued in another Member State of the European Union is concerned and this order contains particulars set forth by the requirements of this Member State[2)].

Section 9

List of medical devices the use and handling of which is generally known

[Implementing Section 56, paragraph 2, letter a) of the Act]

Medical devices the use and handling of which is generally known shall be

a) lubricating gels; and
b) condoms.

Section 10

Particulars of documentation of medical devices in use

(Implementing Section 59, paragraph 4 of the Act)

The documentation of medical devices in use, in respect of which a demonstration must be made, or in respect of which professional maintenance must be conducted on the basis of the manufacturer's instruction, or which are defined as working meters by another legal regulation shall contain the following data:

a) the trade name of the medical device;
b) the name supplement defining the variant of the medical device where it exists;
c) the identification of the medical device comprising of the specification of the manufacturing batch number preceded by the symbol “LOT” or serial number if determined by the manufacturer;
d) the catalogue number of the variant of the medical device allocated by the manufacturer if such number exists;
e) risk class identification or identification of the fact that an active implantable medical device or an *in vitro* diagnostic medical device is concerned;
f) the name of the manufacturer and distributor;
g) the location of the medical device in the healthcare facility of the provider of healthcare services where a fixed-installation medical device is concerned;
h) date of putting into service; and
i) information on completed demonstrations, completed professional maintenance, and completed revisions.

Section 11

Suspected adverse incident reporting and adverse incident reporting

(Implementing Section 71, paragraph 6 of the Act)

(1) Suspected adverse incidents referred to by Section 70, paragraph 2 of the Act and adverse incidents referred to by Section 70, paragraph 1 of the Act shall be notified to the Institute by means of an electronically completed adverse incident report form signed with certified electronic signature pursuant to the guideline of the European Commission on the system of vigilance. The Institute shall publish the form on its website in the Czech and English version.

(2) Providers of healthcare services shall report suspected adverse incidents pursuant to Section 70, paragraph 2 of the Act to the Institute by means of an electronically completed suspected adverse incident report form signed with a certified electronic signature; specimen form is provided in the Annex hereto.

(3) In case of similar adverse incidents occurring in association with the same medical device or type of device and in

respect of which the underlying cause has been established or a field safety corrective action adopted, the manufacturer or authorised representative may report these adverse incidents by means of an electronically completed periodic summary report signed with certified electronic signature pursuant to the guideline of the European Commission on the system of vigilance, which shall be published by the Institute on its website in the Czech and English version. The periodic summary report shall be sent by the manufacturer or authorised representative to the Institute if they agree thereon, including the format, content and frequency of submission of the periodic report.

(4) Forms referred to by paragraphs 1 to 3 shall be sent to the Institute in the PDF format and, concurrently, in the XML format

a) via the web interface;
b) in a data message; or
c) by electronic mail.

Section 12

Scope of information on adverse incident investigation

(Implementing Section 71, paragraph 6 of the Act)

(1) The manufacturer shall collect any information relevant to the investigation of an adverse incident.

(2) In determining the scope of information referred to in paragraph 1, the manufacturer shall always consider the type of the medical device involved in the adverse incident, particularly the method of its use, the results of the conducted analysis, risk analysis and the seriousness and consequences of the adverse incident for the users, patients or other natural persons.

(3) The results of adverse incident investigation shall be reported by the manufacturer or authorised representative to the Institute by means of an electronically completed adverse incident report form signed with a certified electronic signature; the provisions of Section 11, paragraph 4 shall apply accordingly hereto.

Section 13

Field safety corrective actions and safety alerts

(Implementing Section 74, paragraph 5 of the Act)

(1) A manufacturer or authorised representative shall report adopted and completed field safety corrective actions to the Institute by means of an electronically completed field safety corrective action form signed with a certified electronic signature. The field safety corrective action form and the safety alert specimen pursuant to the guideline of the European Commission on the system of vigilance shall be published by the Institute in the Czech and English version. Section 11, paragraph 4 shall apply accordingly to the submission of the form to the Institute.

(2) The manufacturer shall ensure for the importers, distributors, patients, and users of a concerned medical device to be forthwith informed about adopted corrective action by means of a safety alert.

Section 14

Generic groups of medical devices

(Implementing Section 6, paragraph 2 of the Act)

Generic groups of medical devices shall be established on the basis of a numeric code and name as per the Global Medical Device Nomenclature.

Section 15

Effect

This Decree comes into force as of the date of its announcement.

Minister:

MUDr. Němeček, MBA, in his own hand

Annex
Specimen suspected adverse incident report form for reporting by providers of healthcare services

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1) Annex to Implementing Commission Directive 2012/52/EU of 20 December 2012, laying down measures to facilitate the recognition of medical prescriptions issued in another Member State.

2) Art. 11 of Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients´ rights in cross-border healthcare.