90/2021

ACT

of 9 February 2021,

**amending Act No 268/2014 Sb., on Medical Devices and on Amendment to Act No 634/2004 Coll.,
on Administrative Fees, as amended, Act No 634/2004 Coll., on Administrative Fees, as amended, and Act No 40/1995 Coll., on Advertising Regulation and on Amendment to Act
No 468/1991 Coll., on the Operation of Radio and Television Broadcasting, as amended, as amended**

The Parliament adopted the following act of the Czech Republic:

PART ONE

Amendment to the Act on Medical Devices

Article I

Act No 268/2014 Coll., on Medical Devices and on Amendment to Act No 634/2004 Coll., on Administrative Fees, as amended, as amended by Act No 183/2017 Coll. and Act No 366/2017 Coll., is hereby amended as follows:

1. The title of the Act shall read:

"Act on In Vitro Diagnostic Medical Devices".

2. The heading of Part One shall read:

"IN VITRO DIAGNOSTIC MEDICAL DEVICES".

3. Sections 1 to 3, including heading and footnotes no. 1 and 2, shall read:

"Section 1

Subject matter

This Act incorporates the relevant regulations of the European Union (hereinafter referred to as the "Union")[1)] and stipulates the handling of in vitro diagnostic medical devices (hereinafter referred to as "in vitro diagnostic devices") and their accessories.

Basic term definitions

Section 2

(1) A medical device shall mean a medical device referred to by the Act on Medical Devices[2)].

(2) An in vitro diagnostic device shall mean a medical device which is a reagent, reagent product, calibrator, control material, kit, instrument, apparatus, equipment or system, whether used alone or in combination, intended by the manufacturer to be used in vitro for the examination of specimens, including blood and tissue donations, derived from the human body, solely or principally for the purpose of providing information

a) concerning a physiological or pathological state; or

b) concerning a congenital abnormality; or

c) to determine the safety and compatibility with potential recipients; or

d) to monitor therapeutic measures.

(3) Vacuum-type or other-type specimen receptacles specifically intended by their manufacturers for the primary containment and preservation of specimens derived from the human body for the purpose of in vitro diagnostic examination shall be considered to be in vitro diagnostic medical devices. Products for general laboratory use are not in vitro diagnostic medical devices unless such products, in view of their characteristics, are specifically intended by their manufacturer to be used for in vitro diagnostic examination.

Section 3

(1) A device for performance evaluation shall mean an vitro diagnostic device specifically intended by the manufacturer to be subject to one or more performance evaluation studies within the premises of the healthcare service provider or in other appropriate environments with adequate material and technical facilities outside the manufacturer´s own premises.

(2) In vitro diagnostic medical device accessory shall mean an article which, whilst not being an in vitro diagnostic medical device, is intended specifically by its manufacturer to be used together with an in vitro diagnostic device to enable that in vitro diagnostic device to be used in accordance with its intended purpose. Invasive sampling devices or those which are directly applied to the human body for the purpose of obtaining a specimen shall not be considered to be accessories to in vitro diagnostic medical devices.

(3) In vitro diagnostic device for self-testing shall mean any in vitro diagnostic device intended by the manufacturer to be able to be used by persons, who do not need to be healthcare professionals, in a home environment.

(4) In vitro diagnostic device variant shall mean a closer identification of the specific

model or packaging of the in vitro diagnostic device. Individual variants of an in vitro diagnostic device differ, in particular, in size, number of pieces in the packaging, colour scheme or power source. Individual in vitro diagnostic device variants must be identical in respect of their trade name, intended purpose, material composition, and manufacturing process.

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1) Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices, as last amended.
Commission Decision 2010/227/EU of 19 April 2010 on the European Databank on Medical Devices (Eudamed).

2) Act No 89/2021 Coll., on Medical Devices and on Amendment to Act No 378/2007 Coll., on Pharmaceuticals and on Amendments to Some Related Acts (Act on Pharmaceuticals), as amended.".

4. In Section 4(1), in the introductory part of the provision, the words "medical device" shall be replaced with the words "in vitro diagnostic device".

5. In Section 4(2), the words "medical device" shall be replaced with the words " in vitro diagnostic device" and the words "clinical investigation or" shall be deleted.

6. In Section 4(3) and (4), the words "medical device" shall be replaced with the words "in vitro diagnostic device".

7. Section 4(5) shall read:

"(5) Putting into service shall mean the point of time at which an in vitro diagnostic device has been made available for the first time for its intended purpose for use within the territory of a Member State.".

8. Section 4(7) shall read:

"(7) Except for handling referred to under paragraph 1(a), an in vitro diagnostic device may be handled only if it has been assessed in terms of conformity.".

9. In Section 5(a), the words "medical device" shall be replaced with the words "in vitro diagnostic device".

10. Section 5(b) shall read:

"b) sale shall mean the provision of an in vitro diagnostic device to the consumer for his/her own use, including mail-order routes, unless dispensing is concerned;".

11. In Section 5(c), the words "medical device" shall be replaced with the words "in vitro diagnostic device" and the words "medical device" shall be replaced with the words "in vitro diagnostic device".

12. In Section 5(e) and (f), the words "medical device" shall be replaced with the words "in vitro diagnostic device".

13. Section 5(g) shall read:

"g) dispensing person shall mean the person authorised to dispense in vitro diagnostic devices;".

14. In Section 5(h), the words "medical devices" shall be replaced with the words "in vitro diagnostic devices".

15. In Section 5(i), the words "medical device" shall be replaced with the words "in vitro diagnostic device" and the words "medical device" shall be replaced with the words "in vitro diagnostic device".

16. In Section 5(j) and (k), the words "medical device" shall be replaced with the words "in vitro diagnostic device".

17. In Section 5(k) and (l), the words "medical device" shall be replaced with the words "in vitro diagnostic device".

18. Section 5(m) shall be deleted.

The current letter (n) shall become letter (m).

19. Section 5(m) shall read:

"m) an interaction shall mean an undesirable effect between in vitro diagnostic devices or between an in vitro diagnostic device and a medicinal product or an in vitro diagnostic device and other objects during use compliant to their intended purpose.".

20. Section 6, including heading, shall read:

"Section 6

In vitro diagnostic device classification

(1) In vitro diagnostic devices shall be classified by the degree of risk as follows:

a) in vitro diagnostic devices for self-testing;

b) in vitro diagnostic devices per Lists A and B, whereas Lists A and B shall be stipulated by an implementing legal regulation; and

c)
other in vitro diagnostic devices.

(2) In vitro diagnostic devices shall be further classified into generic groups. A generic group of medical devices shall mean a suite of in vitro diagnostic devices of the same or similar intended purpose or common technology, allowing for their generic classification, regardless of the characteristics of the specific in vitro diagnostic device. Generic groups shall be stipulated by an implementing legal regulation.".

21. In the introductory part of the provision stipulated by Section 8 and in Section 8(a), the words "medical devices" shall be replaced with the words "in vitro diagnostic devices".

22. In Section 8(b), the words "medical device" shall be replaced with the words "in vitro diagnostic device".

23. In Section 8(c)(1), the words "medical devices" shall be replaced with the words "in vitro diagnostic devices".

24. In Section 8(d), the words "medical devices" shall be replaced with the words "in vitro diagnostic devices".

25. Section 9, including heading and footnote no. 3, shall read:

"Section 9

Institute

In the area of in vitro diagnostic devices, the Institute shall

a)
decide on whether a product is an in vitro diagnostic device and on its classification, either upon request, or ex-officio;

b)
authorise manufacturers, authorised representatives, importers, distributors, servicing persons, and notified bodies;

c)
notify in vitro diagnostic devices;

d)
via the Registry of Medical Devices, in a manner allowing for remote access, publish

1.
information about registered persons handling in vitro diagnostic devices;

2.
information about notified medical devices; and

3.
information provided by the manufacturer, the authorised representative, importer or distributor in respect of measures aimed at the minimisation of recurrence of incidents referred to by Section 74(2);

e)
safeguard the provision of data to the European databank of medical devices (hereinafter referred to as the "Eudamed");

f)
receive notifications about planned performance study of an in vitro diagnostic device at healthcare service providers and exercise surveillance over their conduct;

g)
perform

1.
the monitoring of the course of investigation into adverse incidents carried out by manufacturers and, where necessary, intervene in their investigation and adopt timely necessary measures,

2.
its own investigation into adverse incidents, where necessary; in this activity, it shall cooperate with the European Commission (hereinafter referred to as the "Commission"), other Member States, and concerned authorities of foreign countries;

3.
the monitoring of efficiency of the conduct of safety corrective actions;

h)
decide on the withdrawal of in vitro diagnostic devices from the market or on their recall in cases of unauthorised use of the CE mark[3)];

i)
decide on the withdrawal of in vitro diagnostic devices from the market or on their recall for technical or health reasons, associated with the characteristics or performance of the in vitro diagnostic device;

j)
be the control authority referred to by this act and the act governing technical requirements for products;

k)
issue certificates of free sale referred to by Section 38(2);

l)
in the area of in vitro diagnostic devices, issue decisions on administrative offences and on the suspension or termination of the use of an in vitro diagnostic device;

m)

within the scope of its powers, represent the Czech Republic in Union workgroups and committees;

n) within the scope of its powers, cooperate with the Office for Standards, Metrology and Testing and with the concerned authorities of foreign countries and of the Union;

o) inform the Commission and concerned authorities of the Member States about decisions issued in compliance with Section 39 along with the reasons leading to their issuance;

p) inform the Commission and the concerned authorities of the Member States about measures adopted or considered in order to minimise recurrence of adverse incidents, including information about such adverse incidents;

q) carry out educational activities, particularly in the form of expert lectures; and

r) upon request, draw up expert opinions and provide expert consultations.

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3) Section 13(3) of Act No 22/1997 Coll., on Technical Requirements for Products and on Amendment to Some Acts, as amended.".

26. In Part One, Title III, the words “CLINICAL EVALUATION AND” shall be deleted from the heading.

27. In Part One, Title III, the identification of Chapter 1 shall be deleted.

28. In Section 10, the words "medical device" shall be replaced with the words "in vitro diagnostic device" and the words "clinical evaluation or" shall be deleted.

29. Part One, Title III, Chapter 2, including heading, shall be deleted.

30. In Part One, Title III, the identification of Chapter 3, including heading, shall be deleted.

31. Sections 23 and 24, including heading, shall read:

"Section 23

Performance evaluation conduct

(1) Performance evaluation shall mean a process resulting in a critical evaluation of data obtained from the use of an in vitro diagnostic medical device in compliance with its intended purpose and verification that it achieves the performance established by the manufacturer in

terms of sensitivity to the relevant analysis, sensitivity to diagnosis, analytical specificity, diagnostic fitness, accuracy, repeatability, reproducibility, minimisation of interference, and detection limit determination.

(2) A performance study shall mean the use of an in vitro diagnostic device within the premises of a healthcare service provider or in another environment with adequate material and technical equipment for the purposes of obtaining data for performance evaluation.

(3) The sponsor of a performance study shall mean a natural person-entrepreneur or legal person who orders the conduct of a performance study and who safeguards the commencement, management, organisation, control, and, where applicable, the financing of performance evaluation. The sponsor of a performance study must be established within the territory of a Member State or must grant a power of attorney to a person established within the territory of a Member State.

(4) Prior to performance study commencement, the performance study sponsor shall be obliged to draw up a study conduct plan and, moreover, ensure that the conduct of the performance study follows this plan. After the end of the performance study, the sponsor shall draw up a final report.

(5) In the conduct of a performance study using tissues or substances of human origin, the sponsor must always assess any and all ethical aspects of the conducted performance study; the outcome of the ethical aspect assessment shall form part of the final report referred to under paragraph (4).

Section 24

Performance study notification

(1) A performance study of an in vitro diagnostic device, which is not CE-marked or which is being used for a purpose other than the original intended purpose within the scope of the performance study, may be conducted at a healthcare service provider established within the territory of the Czech Republic only if notified to the Institute. The notification shall be filed by the performance study sponsor or a person authorised thereby pursuant to Section 23(3), via an electronic form, no later than 30 days prior to the performance study commencement. The declaration referred to under paragraph (2) shall form part of the notification.

(2) In case of an in vitro diagnostic device for performance evaluation, the manufacturer or the authorised representative shall be obliged to draw up a declaration about the in vitro diagnostic device for performance evaluation prior to the performance study commencement. The particulars of the declaration referred to in sentence one shall be stipulated by an implementing legal regulation.

(3) The performance study sponsor shall notify the Institute of the end of the study by means of an electronic form within 30 days of the end of the study and within 6 months of the end of the study shall provide the Institute with the final report for the study in electronic format.

(4) The notifications referred to under paragraphs 1 and 3 shall contain basic study sponsor identification data, the performance study title, data allowing for the identification of the in vitro diagnostic device, which is the subject of the study, basic identification data of the device manufacturer and basic identification data of all healthcare service providers established within the territory of the Czech Republic where the notified study is to be conducted; basic identification data shall mean the basic identification data stipulated by the Code of Administrative Procedure. The notification referred to under paragraph 3 shall, moreover, contain the file number of the notification referred to in paragraph 1 allocated by the Institute. The forms referred to under paragraphs 1 and 3 are published by the Institute on its website.".

32. In Section 25(a) to (c), the word "medical" shall be deleted.

33. Section 25(g) and (h) shall read:

"g) a list of clinical laboratories, where the collection of data for performance evaluation has been conducted outside the premises of the manufacturer;

h) a list of obtained parameters of analytical and diagnostic specificity, sensitivity, including detection limits, accuracy, and repeatability;".

34. In Section 25(i), the words "medical device" shall be replaced with the words "in vitro diagnostic device".

35. In Section 25(j), the word "medical" shall be deleted.

36. In Section 25(k), the words "and place" shall be deleted.

37. In Part One, Title IV, the words "medical devices" shall be replaced with the words "in vitro diagnostic devices" in the heading of Chapter 1.

38. In Section 26(1), the words "medical devices" shall be replaced with the words "in vitro diagnostic devices" and the words "medical devices" shall be replaced with the words "in vitro diagnostic devices".

39. In Section 26(3), the words "risk class I medical devices and in vitro diagnostic medical" shall be replaced with the words "in vitro diagnostic" and the words "medical devices" shall be replaced with the words "in vitro diagnostic devices".

40. Section 26(5) shall be deleted.

The current paragraph 6 shall become paragraph 5.

41. In Section 27(1) and (2), the words "medical devices" shall be replaced with the words "in vitro diagnostic devices".

42. Section 28(2)(c) shall be deleted.

The current letters (d) to (f) shall become letters (c) to (e).

43. In Section 28(2)(d), the words "medical devices" shall be replaced with the words "in vitro diagnostic devices", the text "par. 4(b)" shall be replaced with the text "par. 4(a)" and the text "par. 2(b)" shall be replaced with the text "par. 2(a)".

44. In Section 29(2), the words ", clinical investigation sponsor" shall be deleted.

45. In Section 29(3), the words ", clinical investigation sponsor" shall be deleted.

46. In Section 29(5), the words ", clinical investigation sponsor" shall be deleted.

47. In Part One, Title IV, the words "medical device" in the heading of chapter 2 shall be replaced with the words "in vitro diagnostic device".

48. In the heading of Section 31, the words "medical device" shall be replaced with the words "in vitro diagnostic device".

49. In Section 31(1), the words "medical device" shall be replaced with the words "in vitro diagnostic device", the words "medical device" shall be replaced with the words "in vitro diagnostic device" and the last sentence shall be deleted.

50. In Section 31(2), the words "medical device" shall be replaced with the words "in vitro diagnostic device" and the text "par. 6" shall be replaced with the text "par. 5".

51. In the heading of Section 32, the words "medical device" shall be replaced with the words "in vitro diagnostic device".

52. In Section 32(1) and Section 32(2)(b) to (d) and (f), the words "medical device" shall be replaced with the words "in vitro diagnostic device".

53. Section 32(2)(g) shall read:

"g) information that the in vitro diagnostic device is listed under List A or B or is an in vitro diagnostic device for self-testing or is classified as another in vitro diagnostic device;".

54. Section 32(2)(h) shall be deleted.

The current letters (i) to (n) shall become letters (h) to (m).

55. In Section 32(2)(h) and (i), the words "medical device" shall be replaced with the words "in vitro diagnostic device".

56. In Section 32(2)(j), the words "from the clinical evaluation or" shall be deleted.

57. Section 32(2)(k) shall read:

"k)

the current version of the instructions for use in the Czech language; this condition does not have to be met in case of an in vitro diagnostic device in respect of which the manufacturer has established that instructions for use are not necessary for the safe use of the in vitro diagnostic device;".

58. In the heading of Section 33, the words "medical device" shall be replaced with the words "in vitro diagnostic device".

59. Section 33(1) shall read:

"(1) The distributor or importer of an in vitro diagnostic device shall be obliged to file an application for the device notification with the Institute no later than within 15 days of its placement or supply onto the market in the Czech Republic. This obligation shall not apply to in vitro diagnostic devices that are not listed under List A or List B and are not in vitro diagnostic device for self-testing.".

60. In Section 33(2), the words "medical device" shall be replaced with the words "in vitro diagnostic device" and the words " medical device" shall be replaced with the words "in vitro diagnostic device".

61. In Section 33(3), the words "medical device" shall be replaced with the words "in vitro diagnostic device" and the words "par. 6" shall be replaced with the words "par. 5".

62. In the heading of Section 34, the words "medical device" shall be replaced with the words "in vitro diagnostic device".

63. In Section 34(1) and Section 34(2)(d) to (f), the words "medical device" shall be replaced with the words "in vitro diagnostic device".

64. In Section 34(2)(h) shall read:

"h)

information that the in vitro diagnostic device is listed under List A or B or is an in vitro diagnostic device for self-testing or is classified as another in vitro diagnostic device;".

65. In Section 34(2)(i), the words "medical device" shall be replaced with the words "in vitro diagnostic device".

66. Section 34(2)(j) shall read:

"j)

the current version of the instructions for use in the Czech language; this condition does not have to be met in case of an in vitro diagnostic device in respect of which the manufacturer has established that instructions for use are not necessary for the safe use of the in vitro diagnostic device.".

67. In the heading of Section 35, the words "medical device" shall be replaced with the words "in vitro diagnostic device".

68. In Section 35(1), the words "medical device" shall be replaced with the words "in vitro diagnostic device".

69. In Section 35(2), the words "medical device" shall be replaced with the words "in vitro diagnostic device".

70. In Section 35(3), the words "medical device" shall be replaced with the words "in vitro diagnostic device".

71. In Section 35(4), the words "medical device" shall be replaced with the words "in vitro diagnostic device".

72. In Section 35(5), the words "medical device" shall be replaced with the words "in vitro diagnostic device", the words "medical device" shall be replaced with the words "in vitro diagnostic device" and the words "medical device" shall be replaced with the words "in vitro diagnostic device".

73. In Section 35(6), the words "medical device" shall be replaced with the words "in vitro diagnostic device".

74. In the heading of Section 36, the words "medical device" shall be replaced with the words "in vitro diagnostic device".

75. In Section 36(1), the words "medical device" shall be replaced with the words "in vitro diagnostic device".

76. In Section 37(1), the words "medical device" shall be replaced with the words "in vitro diagnostic device" and the words "medical device" shall be replaced with the words " in vitro diagnostic device".

77. In Section 37(2)(b), the words "medical device" shall be replaced with the words "in vitro diagnostic device".

78. In Section 38(1), the words "medical device" shall be replaced with the words "in vitro diagnostic device".

79. In Section 38(3), the words "medical device" shall be replaced with the words "in vitro diagnostic device".

80. In Section 39(1) sentence one, the words "medical device" shall be replaced with the words "in vitro diagnostic device"; in sentence three, the words ", patients or third parties" shall be inserted after the word "users"; and at the end of the paragraph, the following sentences shall be added: "The decision on withdrawal from the market and recall shall be the first act in the procedure. Appeals from such decisions shall have no suspensory effect.".

81. In the heading of Section 40, the words "medical device" shall be replaced with the words "in vitro diagnostic device".

82. In Section 40(1), the words "medical device" shall be replaced with the words "in vitro diagnostic device".

83. In Section 40(3), the words "medical device" shall be replaced with the words "in vitro diagnostic device".

84. In Section 41(1), in the introductory part of the provision, the words "medical device" shall be replaced with the words "in vitro diagnostic device".

85. In Section 41(1(a) and (b), the words "medical device" shall be replaced with the words "in vitro diagnostic device" and the words "medical device" shall be replaced with the words "in vitro diagnostic device".

86. In Section 41(3), the words "medical device" shall be replaced with the words "in vitro diagnostic device".

87. Section 42(1) shall read:

"(1) An in vitro diagnostic device referred to under Section 6(1)(a) or (b) may be distributed only by a distributor registered by the Institute.".

88. In Section 42(2), the words "medical device" shall be replaced with the words "in vitro diagnostic device referred to under Section 6(1)(a) or (b)".

89. In Section 43, in the introductory part of the provision, the words "Medical device" shall be replaced with the words "In vitro diagnostic device" and the words "medical device" shall be replaced with the words "in vitro diagnostic device".

90. Section 44(1) shall read:

"(1) An in vitro diagnostic device referred to under Section 6(1)(a) or (b) may be imported only by an importer registered by the Institute.".

91. In Section 44(2), the words "medical device" shall be replaced with the words "in vitro diagnostic device referred to under Section 6(1)(a) or (b)".

92. Section 45(1) shall read:

"(1) Only such in vitro diagnostic devices may be distributed or imported, for which a declaration of conformity has been issued and which have been CE-marked.".

93. The introductory part of the provision in Section 45(2) and letter (a) shall read:

"(2) The distributor and the importer shall be obliged to proceed in compliance with good storage and distribution practices which shall mean a suite of rules stipulating the requirements for the maintenance of safety and performance of an in vitro diagnostic device, in particular

a)

to ensure that the in vitro diagnostic device is stored and handled in compliance with its instructions for use and other instructions of the manufacturer;".

94. In Section 45(2)(b), the words "distribution and import" shall be replaced with the words "storage and distribution" and the words "medical device" shall be replaced with the words "in vitro diagnostic device".

95. In Section 45(2)(c) and (d), the words "medical device" shall be replaced with the words "in vitro diagnostic device".

96. In Section 45(2)(e), the words "medical device" shall be replaced with the words "in vitro diagnostic device".

97. In Section 45(2), in the closing part of the provision, the words "distribution and import" shall be replaced with the words "storage and distribution".

98. Section 46, including heading, shall read:

"Section 46

Medical prescription

(1) In vitro diagnostic devices shall be prescribed during the provision of healthcare services by medical doctors or other healthcare professionals of specialised or special professional competence pursuant to the Act on Non-medical Healthcare Professions (hereinafter referred to as the "prescriber") on medical prescription, which shall be

a)

an order for a specific patient issued in paper form; or

b)

a request for an in vitro diagnostic device for use during the provision of healthcare services.

(2) An in vitro diagnostic device shall be dispensed only in case the patient is entitled to its reimbursement pursuant to the act governing public health insurance.

(3) The order may be used at a dispensing person´s no later than within 30 days of its issue, unless specified otherwise by the prescriber, no later, however, than within one year.

(4) The order may not bear symbols or elements that hinder the readability of the completed data, data about other healthcare service providers, or any promotional statements. A blank paper-based order form must not be stamped with the stamp of the healthcare service provider.

(5) An implementing legal regulation stipulates the scope of data to be shown on medical prescription; a medical prescription shall bear data identifying the prescriber, the patient´s health insurance company, the patient for whom the prescribed in vitro diagnostic device is intended, and the prescribed in vitro diagnostic device and the number of pieces

thereof.".

99. Sections 47 and 48, including headings, shall be deleted.

100. Sections 49 to 52, including headings, shall read:

"Section 49

Conditions of dispensing

(1) Only such in vitro diagnostic devices may be dispensed for which a declaration of conformity has been issued and that have been CE-marked.

(2) In vitro diagnostic devices shall be issued on medical prescription. Dispensing shall include also the provision of information necessary for the proper and safe use of the dispensed device.

(3) In vitro diagnostic device may be dispensed solely by a dispensing person who is a pharmacy healthcare service provider.

(4) In vitro diagnostic devices may be dispensed in a pharmacy or in a medical device dispensary only by

a) a pharmacist with professional competence; or

b) a pharmaceutical assistant with professional competence.

Section 50

Mail-order dispensing

(1) A mail-order dispensing shall mean dispensing of an in vitro diagnostic device on order via mail-order service. Offering in vitro diagnostic devices for the purposes of mail-order dispensing and the receipt of orders from persons to carry out mail-order dispensing shall be considered part of mail-order dispensing.

(2) Mail-order dispensing may be carried out only by dispensing persons.

Section 51

Obligations of persons safeguarding mail-order dispensing

In mail-order dispensing of in vitro diagnostic devices, the dispensing person shall be obliged to safeguard:

a)

the publication of information on mail-order dispensing, the offer of an in vitro diagnostic device, its price, the timeline within which it is possible to send the device to the ordering party, and the costs associated with the mail-order dispensing at its website; a mere publication of the offer shall not be considered promotion as referred to by another legal regulation governing advertising;

b)

that the person carrying out mail-order dispensing met the requirements set forth by Section 49(4);

c)

packaging and shipment; the dispensing person shall be responsible for maintaining the quality of the in vitro diagnostic devices, even in case they contract the device shipment with another person;

d)

that shipments were sent to the ordering party no later than within the timeline published as per letter (a) or that the ordering party were forthwith informed by the dispensing person about the reasons for which delivery cannot be executed or will be executed within an extended timeline, including information about such timeline;

e)

an information service provided by a person authorised to dispense the in vitro diagnostic device during defined operating hours; such information service shall also serve for the purposes of collection and hand-over of information about the occurrence of adverse incidents;

f)

the possibility of return of a defective in vitro diagnostic device in a manner through which the ordering party shall incur no costs; such in vitro diagnostic device shall become unusable and the dispensing person shall be obliged to prevent its further distribution.

Section 52

Replacement

(1) In the dispensing of an in vitro diagnostic device prescribed on order, the dispensing individual shall inform the patient about possible alternative options of the prescribed in vitro diagnostic device and, with the patient´s consent, shall be authorised to replace it with another in vitro diagnostic device that is replaceable with the prescribed in vitro diagnostic device in respect of performance and intended purpose. The dispensing individual shall mark the conducted replacement on the order.

(2) If the prescriber, with a view to the patient´s condition of health, or the review doctor of the health insurance company as part of approval of the device reimbursement from the public health insurance insists on the dispensing of the prescribed in vitro diagnostic device, he/she shall make a note on the order reading “Replacement not allowed”. In such a case, the dispensing person may dispense only the prescribed in vitro diagnostic device.".

101. In Section 53, the words "medical device" shall be replaced with the words "in vitro diagnostic device", the words "medical device" shall be replaced with the words "in vitro diagnostic device" and the text "Section 48(2)" shall be replaced with the text "Section 46(3)".

102. In Section 54(a), the words "medical device" shall be replaced with the words "in vitro diagnostic device".

103. In Section 54(b) and (c), the words "medical device" shall be replaced with the words "in vitro diagnostic device".

104. Section 54(d) shall be deleted.

The current letter (e) shall become letter (d).

105. In the introductory part of the provision in Section 55(1), the words "Medical device" shall be replaced with the words "In vitro diagnostic device" and the words "medical device" shall be replaced with the words "in vitro diagnostic device".

106. In Section 55(2), the words "Medical devices" shall be replaced with the words "In vitro diagnostic devices", the words "medical devices" shall be replaced with the words "in vitro diagnostic devices" and the words "medical devices" shall be replaced with the words "in vitro diagnostic devices".

107. In Section 56(1), the words "medical device" shall be replaced with the words "in vitro diagnostic device" and the part of the sentence following the semicolon shall be deleted, incl. the semicolon.

108. Section 56(2)(a) shall read:

"a) safeguard the storage and handling of an in vitro diagnostic device in compliance with instructions for use and other instructions of the manufacturer;".

109. In Section 56(2)(b) and (c), the words "medical device" shall be replaced with the words "in vitro diagnostic device".

110. In Section 56(2)(d), the words "medical device" shall be replaced with the words "in vitro diagnostic device".

111. In the introductory part of the provision in Section 57(1), the words "Medical device" shall be replaced with the words "In vitro diagnostic device" and the words "medical device" shall be replaced with the words "in vitro diagnostic device".

112. In Section 57(2), the words "Medical devices" shall be replaced with the words "In vitro diagnostic devices", the words "medical devices" shall be replaced with the words "in vitro diagnostic devices" and the words "medical devices" shall be replaced with the words "in vitro diagnostic devices".

113. Section 58, including heading, shall read:

"Section 58

General provision

Only an in vitro diagnostic device in respect of which a declaration of conformity has been issued and which has been CE-marked may be used in the provision of healthcare services; this condition shall not be applicable to

a)
the use of an in vitro diagnostic device pursuant to Section 63 or Section 99;

b)
in vitro diagnostic devices that have been manufactured and are used only in the concerned healthcare facility and within the premises where they have been manufactured or premises directly adjacent thereto without being given to another legal entity;

c)
internationally certified reference materials and materials used within external quality system assessment programmes; or

d)
instruments, apparatuses, equipment or other objects, including software, intended for research purposes without any medical objective.".

114. In the heading of Section 59, the words "medical device" shall be replaced with the words "in vitro diagnostic device".

115. Section 59(1)(a) and (b) shall read:

"a)
the in vitro diagnostic device is used in compliance with the manufacturer´s instructions;

b)
prior to each use of an in vitro diagnostic device, the person providing healthcare services is instructed about the necessity to verify the proper technical condition of the device, where such verification of the in vitro diagnostic device is applicable; this requirement shall appropriately apply also to the accessories, software and other products in respect of which it is assumed that they will interact with the concerned in vitro diagnostic medical device;".

116. Section 59(1)(c) and (d) shall be deleted.

The current letters (e) and (f) shall become letters (c) and (d).

117. In Section 59(1)(c), the words "medical device" shall be replaced with the words "in vitro diagnostic device".

118. In Section 59(1)(d), the words "medical device" shall be replaced with the words "in vitro diagnostic device".

119. In the introductory part of the provision in Section 59(2), the words "medical device" shall be replaced with the words "in vitro diagnostic device".

120. In Section 59(2)(a), the words "medical device" shall be replaced with the words "in vitro diagnostic device" and the words "implanted in the human body, where applicable," shall be deleted.

121. In Section 59(2)(d), the words "medical device" shall be replaced with the words "in vitro diagnostic device".

122. In Section 59(2)(e), the words "risk class I or IIa medical devices" shall be replaced with the words "in vitro diagnostic devices" and the words "medical device" shall be replaced with the words "in vitro diagnostic device".

123. Section 59(3) and (4) shall read:

"(3) The provider of healthcare services shall be obliged to keep records of used in vitro diagnostic devices for which

a)
training must be carried out; or

b)
a safety technical control must be conducted as per the manufacturer´s instructions.

(4) The particulars of documentation of used in vitro diagnostic devices shall be set forth by an implementing legal regulation.".

124. Sections 60 and 61, including headings, shall read:

"Section 60

Information for users

The provider of healthcare services shall be obliged to safeguard that any and all information from the instructions for use in the Czech language be made available to the person providing healthcare services via an in vitro diagnostic device. The obligation to safeguard availability of instructions for use shall not apply to an in vitro diagnostic device in respect of which the manufacturer has established that instructions for use are not necessary for the safe use of the device.

Section 61

Training

(1) The healthcare service provider shall be obliged to ensure that an in vitro diagnostic device, in respect of which the manufacturer has established so in the instructions of use, be used or operated in the provision of healthcare services solely by a person who

a)
has completed training for the concerned in vitro diagnostic device, conducted in compliance with the respective instructions for use; and

b)
has been acquainted with the risks associated with the use of the said device.

(2) The training referred to under paragraph 1(a) may be conducted exclusively by

a)
the manufacturer, authorised representative or a person authorised thereby;

b)
a person who has been trained by a person authorised by the manufacturer or authorised representative to conduct such trainings; or

c)
a person who has completed training conducted by a person referred to under letters (a) or (b) and who has at least two years of practical experience in the use of the concerned in vitro diagnostic device, unless the manufacturer or authorised representative stipulates otherwise.

(3) The healthcare service provider shall be obliged to keep and store information about any and all training completed. This information shall be stored thereby for the period of one year of the decommissioning of the in vitro diagnostic device.".

125. Section 62, including heading, shall be deleted.

126. Section 63, including footnotes no. 4 and 5, shall read:

"Section 63

(1) Where healthcare services with the use of in vitro diagnostic devices are provided following the declaration of a state of national emergency, state of war or state of emergency within the territory of the Czech Republic to soldiers on active military duty by military healthcare providers pursuant to the Act on Professional Soldiers[4)], or, if applicable, by other healthcare service providers on the basis of a contract on the provision of healthcare services to professional soldiers concluded with a health insurance company defined by the Act on Public Health Insurance, the Ministry of Defence may adopt a course of action diverting from this Act.

(2) Where the military healthcare service providers as per the Act on Professional Soldiers[4)] provide healthcare services with the use of in vitro diagnostic devices to soldiers on

active military duty commissioned to fulfil tasks of the armed forces of the Czech Republic or the Military Police outside the territory of the Czech Republic[5)], the Ministry of Defence may adopt a course of action diverting from this Act.

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4) Section 94(2) of Act No 221/1999 Coll., on Professional Soldiers, as amended.

5) Article 43 of Constitutional Act No 12/1993 Coll., the Constitution of the Czech Republic, as amended.
Section 3(1) of Act No 300/2013 Coll., on Military Police and Amendments to Some Acts (Military Police Act), as amended.".

127. In Section 64(1), the words "medical device" shall be replaced with the words "in vitro diagnostic device" and the part of the sentence following semicolon shall be deleted, including the semicolon.

128. In Section 64(2), the words "medical device" shall be replaced with the words "in vitro diagnostic device".

129. In Section 64(3), the words "medical device" shall be replaced with the words "in vitro diagnostic device".

130. Sections 65 and 66, including headings and footnote no. 6, shall read:

"Section 65

Safety technical control

(1) A safety technical control shall mean the performance of regular actions aimed at the maintenance of safety and full functionality of the in vitro diagnostic device.

(2) A safety technical control shall also include the performance of electrical control of an in vitro diagnostic device that is electrical equipment. For the purposes of this Act, electrical equipment shall mean equipment that may jeopardise life, health or property by electrical current. The electrical control of the device shall be conducted in a manner prescribed by the manufacturer; where the procedure has not been defined by the manufacturer, the procedure described in the technical standard governing medical electrical equipment shall be used[6)].

(3) The safety technical control shall be conducted for the in vitro diagnostic device to the extent and in frequency prescribed by the manufacturer. Where the manufacturer does not define the frequency of safety technical controls of an in vitro diagnostic device that is electrical equipment, the safety technical control shall be performed at least every two years. Such control must be conducted no later than in the calendar month in the course of which the timeline for the performance of the safety technical control expires.

(4) The servicing person who performs the safety technical control shall be obliged to

a)

provably safeguard an up-to-date training of all staff performing the safety technical control by the person referred to under Section 61(2)(a) or (b) within the scope defined by the manufacturer;

b)

ensure that the safety technical control of an in vitro diagnostic device be performed solely by

1.
an employee with professional competence to conduct the profession of a biomedical technician or biomedical engineer;

2.
an employee who completed a university bachelor´s or master´s degree in the area of education covering machinery, technologies and materials or electrotechnology or a similar university degree obtained from a higher-education school not classified as the aforementioned area of education and with at least a three-month professional practical experience in the area of safety technical controls of in vitro diagnostic devices;

3.
an employee with secondary technical education concluded by a general certificate of education or a higher technical education and at least six months of professional practical experience in the area of safety technical controls of in vitro diagnostic devices;

4.
an employee with secondary education concluded by a general certificate of education and at least one year of professional practical experience in the area of safety technical controls of in vitro diagnostic devices; or

5.
an employee who completed a university bachelor´s or master´s degree in the area of education covering machinery, technologies and materials or electrotechnology or a similar university degree obtained from a higher-education school not classified as the aforementioned area of education or with secondary education concluded by a general certificate of education or a higher technical education under the direct supervision by a person referred to under point 1, 2, 3 or 4; such conduct of safety technical control of in vitro diagnostic devices shall be considered practical experience for the purposes of points 2, 3, and 4;

c)

where safety technical control of an in vitro diagnostic device that is electrical equipment is concerned, ensure that in addition to the requirements set forth by letters (a) and (b), the staff conducting this safety technical control also met the requirements for

1.

staff conducting independent activity as per another legal regulation governing professional competence in electrotechnology; or

2.
cognisant staff as referred to under another legal regulation governing professional competence in electrotechnology under the supervision by a person defined in point 1; and

d)
provide for adequate material and technical facilities for the conduct of the safety technical control.

(5) Following the completion of safety technical control, the servicing person must ensure that the staff performing the safety technical control draw up and sign a record thereof. Where the safety technical control is performed by a person defined under paragraph (4)(b)(5), the record shall be signed also by the person performing direct supervision. The healthcare service provider shall be obliged to keep this record throughout the use of the in vitro diagnostic device as well as for the period of one year after the decommissioning of the in vitro diagnostic device.

Section 66

Repair

(1) A repair shall mean a set of actions through which the original or operable and safe condition of a damaged in vitro diagnostic device is reinstated without changing the technical parameters or intended purpose thereof.

(2) The servicing person who performs the repair shall be obliged to

a)
provably safeguard an up-to-date training in the area of repairs of the concerned in vitro diagnostic device for all staff performing the repair by the person referred to under Section 61(2)(a) or (b) within the scope defined by the manufacturer;

b)
ensure that the repair of an in vitro diagnostic device be performed solely by

1.
an employee with professional competence to conduct the profession of a biomedical technician or a biomedical engineer;

2.
an employee who completed a university bachelor´s or master´s degree in the area of education covering machinery, technologies and materials or electrotechnology or a similar university degree obtained from a higher-education school not classified as the aforementioned area of education and with at least a three-month professional practical experience in the area of in vitro diagnostic device repairs;

3.
an employee with secondary technical education concluded by a general certificate of education or a higher technical education and at least six months of professional practical experience in the area of in vitro diagnostic device repairs;

4.
an employee with secondary education concluded by a general certificate of education and at least one year of professional practical experience in the area of in vitro diagnostic device repairs; or

5.
an employee who completed a university bachelor´s or master´s degree in the area of education covering machinery, technologies and materials or electrotechnology or a similar university degree obtained from a higher-education school not classified as the aforementioned area of education, or with secondary education concluded by a general certificate of education or a higher technical education under the direct supervision by a person referred to under point 1, 2, 3 or 4; such conduct of in vitro diagnostic device repairs shall be considered practical experience for the purposes of points 2, 3, and 4;

c)
where repair of an in vitro diagnostic device that is electrical equipment is concerned, ensure that in addition to the requirements set forth by letters (a) and (b), the staff conducting this repair also met the requirements for

1.
staff conducting independent activity as per another legal regulation governing professional competence in electrotechnology; or

2.
cognisant staff as referred to under another legal regulation governing professional competence in electrotechnology under the supervision by a person defined in point 1;

d)
where repair of an in vitro diagnostic device which includes a pressure mechanism is concerned, ensure that the repair of the pressure mechanism is conducted by staff who meet the requirements governing professional competence for the repairs of pressure mechanisms stipulated by another legal regulation;

e)
where repair of an in vitro diagnostic device which includes a gas appliance is concerned, ensure that the repair of the gas appliance is conducted by staff who meet the requirements governing professional competence for the repairs of gas appliances stipulated by another legal regulation; and

f)
provide for adequate material and technical facilities for the conduct of repairs.

(3) After the completion of the repair, the servicing person must ensure that the staff conducting the repair test the safety and functionality of the in vitro diagnostic device and draw up and sign a record about the repair and testing. Where the repair is conducted by the

person referred to under paragraph (2)(b)(5), the record shall be signed also by the person performing direct supervision. The healthcare service provider shall be obliged to keep this record throughout the use of the in vitro diagnostic device as well as for the period of one year after the decommissioning of the vitro diagnostic device.

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6) ČSN EN 62353 - Zdravotnické elektrické přístroje - Opakované zkoušky a zkoušky po opravách zdravotnických elektrických přístrojů (Medical electrical equipment - Recurrent test and test after repair of medical electrical equipment).".

131. In Section 67(1), the words "medical device" shall be replaced with the words "in vitro diagnostic device".

132. Section 67(2) to (4) shall be deleted and the heading of paragraph 1 shall be deleted.

133. Section 68, including heading, shall be deleted.

134. In Section 69(1), the words "medical devices" shall be replaced with the words "in vitro diagnostic devices".

135. Section 69(2) shall read:

"(2) An adverse incident shall mean

a) any malfunction, failure or deterioration in the characteristics and/or performance of an in vitro diagnostic device, as well as any inadequacy in the labelling of an in vitro diagnostic device or the instructions for use which, directly or indirectly, might lead to or might have led to the death of a patient or user or of other natural persons or to a serious deterioration in their state of health;

b) any technical or medical reason in relation to the characteristics or performance of an in vitro diagnostic device for the reasons referred to under letter (a), leading to systematic recall of in vitro diagnostic devices of the same type by the manufacturer.".

136. In Section 69(3), the words "medical device" shall be replaced with the words "in vitro diagnostic device".

137. In Section 70(1), the words "medical device" shall be replaced with the words "in vitro diagnostic device".

138. In Section 70(2), Section 70(3)(b), and Section 70(4), the words "medical device" shall be replaced with the words "in vitro diagnostic device".

139. In Section 71(2), the words "medical devices" shall be replaced with the words "in vitro diagnostic devices" and the words "medical devices" shall be replaced with the words

"in vitro diagnostic devices".

140. In Section 71(3)(a), the words "medical device" shall be replaced with the words "in vitro diagnostic device".

141. In Section 72(1) the word "patient" shall be followed by the words "in association with the use of an in vitro diagnostic device".

142. In the introductory part of the provision in Section 73, the words "medical device" shall be replaced with the words "in vitro diagnostic device".

143. In Section 73(b), the words "medical device" shall be replaced with the words "in vitro diagnostic device".

144. In Section 74(2), the words "established within the territory of the Czech Republic" shall be deleted; the word "action" shall be followed by the words "that is to be implemented within the territory of the Czech Republic," and the words "medical device" shall be replaced with the words "in vitro diagnostic device".

145. In Section 74(5), the text "paragraph 2" shall be followed by text "and 4".

146. In Section 75(b) and (c), the numeral "10" shall be replaced with numeral "15".

147. In the introductory part of the provision in Section 76(1), the words "medical device" shall be replaced with the words "in vitro diagnostic device" and the words "medical device" shall be replaced with the words "in vitro diagnostic device".

148. In Section 76(2), the words "medical device" shall be replaced with the words "in vitro diagnostic device".

149. The words "MEDICAL DEVICE NATIONAL INFORMATION SYSTEM AND" shall be deleted from the first part of the heading of Title XII".

150. Section 77, including heading, shall be deleted.

151. In Section 78(1)(a), the words "placed on the market in the Czech Republic;" shall be replaced with the words "and in vitro diagnostic devices placed on or supplied onto the market or in operation within the territory of the Czech Republic;".

152. In Section 78(1), the words "or the Act on Medical Devices" shall be added to the end of the text in letter (b).

153. In Section 78(1) the words "conducted pursuant to the Act on Medical Devices[2)] and" shall be added to the end of the text under letter (d).

154. Section 78(1)(e) shall be deleted.

The current letter (f) shall become letter (e).

155. Section 78(2) shall be deleted.

The current paragraphs 3 and 4 shall become paragraphs 2 and 3.

156. Section 78(3) shall be deleted.

157. In Section 79(1)(a) and (b), the words "and in vitro diagnostic devices" shall be added after the words "medical devices".

158. In Section 79(1), the words "and in vitro diagnostic devices" shall be added at the end of the text under letters (c) and (d).

159. In Section 80(1), the words "medical devices" shall be replaced with the words "in vitro diagnostic devices".

160. In Section 80(2), the words "medical devices" shall be replaced with the words "in vitro diagnostic devices".

161. In Section 80(4), the word "suspension" shall be replaced with the word "restriction" and the words "medical device" shall be replaced with the words "in vitro diagnostic device".

162. Section 81, including heading, shall read:

"Section 81

Offences by legal persons and natural persons-entrepreneurs in the field of performance evaluation

(1) The sponsor of a performance evaluation study shall be deemed to have committed an offence by

a) failing to meet the notification duty referred to under Section 24(1); or

b) failing to provide the final report contrary to Section 24(3).

(2) A fine for an offence may be imposed up to the amount of

a) 500,000 CZK, where an offence referred to under paragraph 1(a) is concerned;

b) 200,000 CZK, where an offence referred to under paragraph (1)(b) is concerned.".

163. Section 82, including heading, shall be deleted.

164. In Section 83(1), the comma following the word "distributor" shall be deleted and

the word "or" shall be added and the words "or sponsor of a clinical investigation" shall be deleted.

165. In Section 83(2), the words "sponsor of a clinical investigation" shall be deleted.

166. In the heading of Section 84, the words "medical device" shall be replaced with the words "in vitro diagnostic device".

167. In Section 84(1)(a) and (b), the words "medical device" shall be replaced with the words "in vitro diagnostic device".

168. In the heading of Section 85, the words "medical device" shall be replaced with the words "in vitro diagnostic device".

169. In Section 85(1), in the introductory part of the provision and in letters (a) and (c), the words "medical device" shall be replaced with the words "in vitro diagnostic device".

170. In Section 86(1) and Section 86(2)(a), the words "medical device" shall be replaced with the words "in vitro diagnostic device".

171. In Section 86(2)(b), the words "distribution and import" shall be replaced with the words "storage and distribution".

172. Section 86(3)(b) shall be deleted.

The current letters (c) to (e) shall become letters (b) to (d).

173. In Section 86(3)(c), the words "medical device" shall be replaced with the words "in vitro diagnostic device".

174. In Section 86(3)(d), the words "medical devices" shall be replaced with the words "in vitro diagnostic devices" and the words "medical devices" shall be replaced with the words "in vitro diagnostic devices".

175. In Section 86(4)(a) and (c), the words "medical device" shall be replaced with the words "in vitro diagnostic device".

176. In Section 86(4)(d), the words "medical devices" shall be replaced with the words "in vitro diagnostic devices" and the words "medical devices" shall be replaced with the words "in vitro diagnostic devices".

177. Section 86(5) and (6) shall read:

"(5) A legal person or natural person-entrepreneur shall be deemed to have committed an offence by failing to meet any of the obligations set forth by Section 50(2) in mail-order dispensing of an in vitro diagnostic device.

(6) A fine for an offence may be imposed up to the amount of

a)
200,000 CZK, where an offence referred to under paragraph 2(a), paragraph 3(d), and paragraph 4(d) is concerned;

b)
500,000 CZK, where an offence referred to under paragraph 1, paragraph 2(b), paragraph 3(a), (b) or (c), and paragraph 4(a), (b) or (c) is concerned;

c)
1,000,000 CZK, where an offence referred to under paragraph 5 is concerned.".

178. In Section 87(1), the words "which is an order" shall be deleted.

179. Section 87(2) shall read:

"(2) A natural person as an employee authorised to prescribe in vitro diagnostic devices in the provision of healthcare services shall be deemed to have committed an offence by failing to meet any of the obligations set forth under Section 46(4).".

180. Section 87(3) shall be deleted.

The current paragraph 4 shall become paragraph 3.

181. In Section 87(3)(b), the final semicolon shall be replaced with a full stop and letter (c) shall be deleted.

182. In Section 88(1), the words "which is an order" shall be deleted.

183. Section 88(2) shall read:

"(2) A natural person-entrepreneur authorised to prescribe in vitro diagnostic devices in the provision of healthcare services shall be deemed to have committed an offence by failing to meet any of the obligations set forth under Section 46(4).".

184. In Section 89(1)(a), the words "medical device" shall be replaced with the words "in vitro diagnostic device".

185. Section 89(1)(c) shall read:

"c)
failing to ensure that information from the instructions for use be made available to the person providing healthcare services as referred to under Section 60;".

186. In Section 89(1)(d) and Section 89(1)(e)(1), the words "medical device" shall be replaced with the words "in vitro diagnostic device".

187. In Section 90(1), the words "medical device" shall be replaced with the words "in vitro diagnostic device".

188. In Section 90(3) and (5), the word "protocol" shall be replaced with the word

"record".

189. In Section 92(1), the words ", except for offences referred to under Section 87(3) handled by a municipal authority with enlarged jurisdiction" shall be deleted.

190. Section 93, including heading, shall read:

"Section 93

Accessories and other use of in vitro diagnostic devices

The provisions of this Act stipulating the requirements for in vitro diagnostic devices and for persons handling in vitro diagnostic devices shall be applicable to the accessories of in vitro diagnostic devices and persons handling such accessories by analogy.".

191. Sections 94 and 95, including heading, shall read:

"Reimbursement of costs of expert activities

Section 94

(1) The applicant shall be obliged to reimburse to the Institute the costs of expert activities conducted by the Institute upon the applicant´s request.

(2) The applicant shall be obliged to reimburse the costs of the Institute´s expert activities associated with

a)
the drawing up of an expert opinion or position as referred to under Section 9(r);

b)
the provision of expert consultations as referred to under Section 9(r); or

c)
the preparation and conduct of training activities as referred to under Section 9(q).

(3) The specification of expert activities, the method of determination of the amount of reimbursement of costs of the conduct of expert activities within the scope of individual tasks, the maximum amount of reimbursement of costs of the conduct of expert activities within the scope of individual tasks, and the amount of advance payments for the reimbursement of costs of the conduct of expert activities within the scope of individual tasks shall be stipulated by an implementing legal regulation. The amount of reimbursement of costs of the conduct of expert activities within the scope of individual tasks shall be determined as an amount covering the costs of the conduct of these expert activities to the necessary extent.

Section 95

(1) The person upon whose request the expert activities are to be performed shall be

obliged to pay the Institute an advance payment for the reimbursement of costs if it is obvious that the expert activities will be performed. Where expert activities referred to under Section 94(2)(a) to (c) are concerned, the Institute shall publish the usual amount of time necessary for the completion of the individual activities on its website.

(2) The Institute shall refund the reimbursement of costs to the applicant upon the latter´s request

a) in full amount if the applicant has paid the reimbursement of costs without being obliged to do so;

b) in full amount if the required expert activity has not been commenced; or

c) in the amount corresponding to the pro rata amount of the paid reimbursement of costs of expert activities that have not been performed.

(3) The applicant shall pay the difference between the advance payment for the reimbursement of costs as referred to under paragraph (1) and the actual amount of reimbursement of costs where the actual amount of reimbursement of costs is greater than the advance payment, and shall do so within the timeline stipulated by the Institute in the invitation to pay the balance of reimbursement of costs.

(4) Reimbursement of costs referred to under Section 94 shall not be a state budget income as per another legal regulation[7)], but the income of the Institute and shall be kept at a special account forming part of the Institute´s reserve fund. The Institute shall use such funds to safeguard its operation pursuant to this Act or to other legal regulations, where such operation cannot be covered from budgetary funds in the necessary scope.

(5) Where the government decides so, the Institute shall transfer an amount defined by the government from the account kept as per paragraph (4) to the income account of the state budget of the Czech Republic opened for the Ministry of Health.".

192. Section 96(2) shall read:

"(2) The Ministry shall issue a decree implementing Section 6(2), Section 45(2), Section 46(5), Section 59(4), Section 71(6), Section 74(5), and Section 94(3).".

193. In sentence one of Section 99(1), the words "medical device" shall be replaced with the words "in vitro diagnostic device", the words "or in case of a diagnosis of a life-threatening or chronically debilitating condition affecting no more than five persons out of 10,000" shall be added after the word "health" and the words "medical device" shall be replaced with the words "in vitro diagnostic device".

194. In Section 100(1), the words "clinical investigations of medical devices, members of ethics committees" shall be replaced with the words "in vitro diagnostic device performance studies".

195. In Section 100(2)(a), the words "medical devices" shall be replaced with the words "in vitro diagnostic devices".

Article II

Transitional provisions

1. A person who, as at the date of entry into force of this Act, has gained at least one-year practical experience in the conduct of safety technical controls of in vitro diagnostic devices shall be considered a person meeting the requirement for professional qualification referred to under Section 65(4(b) of Act No 268/2014 Coll., as amended as at the date of entry into force hereof.

2. A person who, as at the date of entry into force of this Act, has gained at least one-year practical experience in the conduct of repairs of the concerned in vitro diagnostic device or a similar-type in vitro diagnostic device shall be considered a person meeting the requirement for professional qualification referred to under Section 66(2)(b) of Act No 268/2014 Coll., as amended as at the date of entry into force hereof.

3. Performance evaluations initiated prior to the date of entry into force of this Act shall be completed in compliance with Act No 268/2014 Coll., as amended prior to the date of entry into force hereof.

PART TWO

Amendment to the Act on Administrative Fees

Article III

Annex to Act No 634/2004 Coll., on Administrative Fees, as amended by Act No 217/2005 Coll., Act No 228/2005 Coll., Act No 361/2005 Coll., Act No 444/2005 Coll., Act No 545/2005 Coll., Act No 553/2005 Coll., Act No 48/2006 Coll., Act No 56/2006 Coll., Act No 57/2006 Coll., Act No 81/2006 Coll., Act No 109/2006 Coll., Act No 112/2006 Coll., Act No 130/2006 Coll., Act No 136/2006 Coll., Act No 138/2006 Coll., Act No 161/2006 Coll., Act No 179/2006 Coll., Act No 186/2006 Coll., Act No 215/2006 Coll., Act No 226/2006 Coll., Act No 227/2006 Coll., Act No 235/2006 Coll., Act No 312/2006 Coll., Act No 575/2006 Coll., Act No 106/2007 Coll., Act No 261/2007 Coll., Act No 269/2007 Coll., Act No 374/2007 Coll., Act No 379/2007 Coll., Act No 38/2008 Coll., Act No 130/2008 Coll., Act No 140/2008 Coll., Act No 182/2008 Coll., Act No 189/2008 Coll., Act No 230/2008 Coll., Act No 239/2008 Coll., Act No 254/2008 Coll., Act No 296/2008 Coll., Act No 297/2008 Coll., Act No 301/2008 Coll., Act No 309/2008 Coll., Act No 312/2008 Coll., Act No 382/2008 Coll., Act No 9/2009 Coll., Act No 141/2009 Coll., Act No 197/2009 Coll., Act No 206/2009 Coll., Act No 227/2009 Coll., Act No 281/2009 Coll., Act No 291/2009 Coll., Act No 301/2009 Coll., Act No 346/2009 Coll., Act No 420/2009 Coll., Act No 132/2010 Coll., Act No 148/2010 Coll., Act No 153/2010 Coll., Act No 160/2010 Coll., Act No 343/2010 Coll., Act No 427/2010 Coll., Act No 30/2011 Coll., Act No 105/2011 Coll., Act No 133/2011 Coll., Act No 134/2011 Coll., Act No 152/2011 Coll., Act No 188/2011 Coll., Act No 245/2011 Coll., Act No 249/2011 Coll., Act No 255/2011 Coll., Act No 262/2011 Coll., Act No 300/2011 Coll., Act No 308/2011 Coll., Act No 329/2011 Coll., Act No

344/2011 Coll., Act No 349/2011 Coll., Act No 350/2011 Coll., Act No 357/2011 Coll., Act No 367/2011 Coll., Act No 375/2011 Coll., Act No 428/2011 Coll., Act No 458/2011 Coll., Act No 472/2011 Coll., Act No 19/2012 Coll., Act No 37/2012 Coll., Act No 53/2012 Coll., Act No 119/2012 Coll., Act No 169/2012 Coll., Act No 172/2012 Coll., Act No 202/2012 Coll., Act No 221/2012 Coll., Act No 225/2012 Coll., Act No 274/2012 Coll., Act No 350/2012 Coll., Act No 359/2012 Coll., Act No 399/2012 Coll., Act No 407/2012 Coll., Act No 428/2012 Coll., Act No 496/2012 Coll., Act No 502/2012 Coll., Act No 503/2012 Coll., Act No 50/2013 Coll., Act No 69/2013 Coll., Act No 102/2013 Coll., Act No 170/2013 Coll., Act No 185/2013 Coll., Act No 186/2013 Coll., Act No 232/2013 Coll., Act No 239/2013 Coll., Act No 241/2013 Coll., Act No 257/2013 Coll., Act No 273/2013 Coll., Act No 279/2013 Coll., Act No 281/2013 Coll., Act No 306/2013 Coll., Act No 313/2013 Coll., Senate Legislative Measure No 344/2013 Coll., Act No 101/2014 Coll., Act No 127/2014 Coll., Act No 187/2014 Coll., Act No 249/2014 Coll., Act No 257/2014 Coll., Act No 259/2014 Coll., Act No 264/2014 Coll., Act No 268/2014 Coll., Act No 331/2014 Coll., Act No 81/2015 Coll., Act No 103/2015 Coll., Act No 204/2015 Coll., Act No 206/2015 Coll., Act No 224/2015 Coll., Act No 268/2015 Coll., Act No 314/2015 Coll., Act No 318/2015 Coll., Act No 113/2016 Coll., Act No 126/2016 Coll., Act No 137/2016 Coll., Act No 148/2016 Coll., Act No 188/2016 Coll., Act No 229/2016 Coll., Act No 243/2016 Coll., Act No 258/2016 Coll., Act No 264/2016 Coll., Act No 298/2016 Coll., Act No 319/2016 Coll., Act No 324/2016 Coll., Act No 369/2016 Coll., Act No 63/2017 Coll., Act No 170/2017 Coll., Act No 194/2017 Coll., Act No 195/2017 Coll., Act No 199/2017 Coll., Act No 202/2017 Coll., Act No 204/2017 Coll., Act No 206/2017 Coll., Act No 222/2017 Coll., Act No 225/2017 Coll., Act No 251/2017 Coll., Act No 261/2017 Coll., Act No 289/2017 Coll., Act No 295/2017 Coll., Act No 299/2017 Coll., Act No 302/2017 Coll., Act No 304/2017 Coll., Act No 371/2017 Coll., Act No 90/2018 Coll., Act No 171/2018 Coll., Act No 193/2018 Coll., Act No 286/2018 Coll., Act No 307/2018 Coll., Act No 135/2019 Coll., Act No 176/2019, Act No 209/2019 Coll., Act No 255/2019 Coll., Act No 277/2019 Coll., Act No 279/2019 Coll., Act No 12/2020 Coll., Act No 115/2020 Coll., Act No 119/2020 Coll., Act No 334/2020 Coll., Act No 337/2020 Coll., and Act No 501/2020 Coll., shall be amended as follows:

1. Item 97(3) shall read:

"3. Receipt of

a)

application of notification or renewal of notification of a serially manufactured in vitro diagnostic medical device or accessories of an in vitro diagnostic medical device placed on the market by the manufacturer or authorised representative

CZK 500

b)

notification of operation of a manufacturer of serially manufactured in vitro diagnostic medical devices

CZK 3,000

c)

notification of operation of an authorised representative pursuant to the Act on In Vitro Diagnostic Medical Devices

CZK 3,000

d)

notification of operation of a distributor of in vitro diagnostic medical devices

CZK 3,000

e)

notification of operation of a person servicing in vitro diagnostic medical devices

CZK 3,000

f)

notification of operation of an importer of in vitro diagnostic medical devices

CZK 3,000

g)

application for the issue of certificate of free sale for an in vitro diagnostic medical device

CZK 1,000".

2. Points 4 and 5 shall be added to item 97 and they shall read:

"4.

Verification of data pursuant to Art. 31(1) 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 "Medical Device Regulation") and the allocation of the single registration number (SRN) as per Art. 31(2) of the Medical Device Regulation to the manufacturer, authorised representative or importer

CZK 3,000

5. Receipt of

a) notification of the commencement of operation of a manufacturer of custom-made medical devices

CZK 3,000

b) notification of the commencement of operation of a medical device distributor

CZK 3,000

c) notification of the commencement of operation of a person servicing medical devices

CZK 3,000

d) application for renewal of invalidated data of a notified person in the Medical Device Information System

CZK 1,500

e) application for authorisation of a clinical investigation of a medical device

CZK 1,000

f) application for the issue of a certificate of free sale for a medical device

CZK 1,000".

PART THREE

Amendment to the Act on Advertising Regulation

Article IV

Act No 40/1995 Coll., on Advertising Regulation and on Amendment to Act No

468/1991 Coll., on the Operation of Radio and Television Broadcasting, as amended, as amended by Act No 258/2000 Coll., Act No 231/2001 Coll., Act No 256/2001 Coll., Act No 138/2002 Coll., Act No 320/2002 Coll., Act No 132/2003 Coll., Act No 217/2004 Coll., Act No 326/2004 Coll., Act No 480/2004 Coll., Act No 384/2005 Coll., Act No 444/2005 Coll., Act No 25/2006 Coll., Act No 109/2007 Coll., Act No 160/2007 Coll., Act No 36/2008 Coll., Act No 296/2008 Coll., Act No 281/2009 Coll., Act No 132/2010 Coll., Act No 28/2011 Coll., Act No 245/2011 Coll., Act No 375/2011 Coll., Act No 275/2012 Coll., Act No 279/2013 Coll., Act No 303/2013 Coll., Act No 202/2015 Coll., Act No 180/2016 Coll., Act No 188/2016 Coll., Act No 26/2017 Coll., Act No 66/2017 Coll., Act No 183/2017 Coll., Act No 299/2017 Coll., and Act No 238/2020 Coll., shall be amended as follows:

1. In Section 1(1), the words ", for medical devices and in vitro diagnostic medical devices" shall be added after the words "veterinary medicinal products".

2. At the end of footnote no. 1, the following sentence shall be added: "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.".

3. Section 2a shall read:

"Section 2a

Comparative advertising for medicinal products intended for administration to humans (hereinafter referred to as "human medicinal products"), for healthcare services, medical devices or in vitro diagnostic medical devices shall be permissible providing the conditions stipulated by the Civil Code have been met and it is focused upon persons authorised to prescribe or dispense these medicinal products, medical devices or in vitro diagnostic medical devices (hereinafter referred to as "professionals") and/or to provide these healthcare services.".

4. New Sections 5k to 5m shall be added after Section 5j and including headings and footnotes 42 to 44 they shall read:

"Section 5k

Medical devices and in vitro diagnostic medical devices

(1) Any forms of provision of information, surveys or incentives conducted for the purposes of supporting the prescription, dispensing, sale or use of medical devices and in vitro diagnostic medical devices shall be also considered to be advertising for medical devices and in vitro diagnostic medical devices. These concern, in particular

a) visits of salespeople with medical devices and in vitro diagnostic medical devices to persons authorised to prescribe or sell such devices;

b)

provision of specimen medical devices and in vitro diagnostic medical devices;

c) support of prescribing, dispensing or sale of medical devices or in vitro diagnostic medical devices through the provision of gifts, consumer competitions and offers or promise of any benefit or financial or material reward;

d) sponsoring of meetings held for the purposes of support of prescribing, sale, dispensing or use of medical devices or in vitro diagnostic medical devices and attended by professionals; or

e) sponsoring of scientific congresses and other similar meetings attended by professionals and the reimbursement of costs of travel and lodging arising from their participation.

(2) The provisions of the Act shall not be applicable to

a) correspondence necessary to answer specific questions regarding a concrete medical device or in vitro diagnostic medical device and background materials of non-promotional nature, if applicable;

b) sales catalogues and price lists, unless they contain a description of the characteristics of medical devices and in vitro diagnostic medical devices;

c) data about the health of people or diseases unless they contain any reference, including indirect ones, to the medical device or in vitro diagnostic medical device.

(3) The subject of advertising may only be a medical device that may be placed on the market in compliance with Regulation (EU) 2017/745 of the European Parliament and of the Council[42)] or an in vitro diagnostic medical device that may be placed onto the market in compliance with another legal regulation governing in vitro diagnostic medical devices[43)], unless specified otherwise hereunder.

(4) A medical device not meeting the conditions for placement onto the market pursuant to Regulation (EU) 2017/745 of the European Parliament and of the Council[42)] may be presented or demonstrated only at trade fairs, exhibitions, and demonstration or similar events, providing that it has been labelled in compliance with Regulation (EU) 2017/745 of the European Parliament and of the Council[44)].

(5) An in vitro diagnostic medical device not meeting the conditions for placement onto the market may be presented or demonstrated only at trade fairs, exhibitions, and demonstration or similar events, providing that it has been visibly labelled as a device that may not be placed onto the market or into operation until its conformity is achieved. Such in vitro diagnostic medical device must not be used with samples from the attendees of the event referred to in sentence one.

(6) Advertisements for in vitro diagnostic medical devices must not contain texts, names, trademarks, images and figurative or other symbols that could mislead the patient in terms of the intended purpose, safety, and performance of the in vitro diagnostic medical device through

a) suggesting functions or properties that the in vitro diagnostic medical device does not have;

b) creating a false idea regarding treatment or diagnosis, functions or properties that the in vitro diagnostic medical device does not have;

c) failing to inform the user or patient about likely risks associated with the use of the in vitro diagnostic medical device in compliance with its intended purpose; or

d) proposing alternative ways of using the in vitro diagnostic medical device than those specified in the intended purpose.

(7) Advertising for medical devices and in vitro diagnostic medical devices fully or partially reimbursed from public health insurance funds in the form of a consumer competition based on the number of prescribed, dispensed or used devices is prohibited.

(8) Advertising for medical devices and in vitro diagnostic medical devices must not refer to specific state administration authorities in any manner.

Section 5l

Advertising for medical devices and in vitro diagnostic medical devices targeted at the general public

(1) A medical device and an in vitro diagnostic medical device that is, according to the manufacturer´s instructions, intended solely for use by a healthcare professional and a medical device and in vitro diagnostic medical device that may be dispensed only on order or request form issued by a doctor pursuant to other legal regulations must not be the subject of advertising targeted at the general public.

(2) The provision of specimen medical devices and in vitro diagnostic medical devices referred to under paragraph 1 to the general public is prohibited.

(3) Advertising for a medical device and an in vitro diagnostic medical device targeted at the general public must

a)

be worded in a manner that clearly demonstrates that the product is a medical device or an in vitro diagnostic medical device;

b)
contain the trade name of the medical device and in vitro diagnostic medical device;

c)
contain the intended purpose of the medical device and in vitro diagnostic medical device; and

d)
contain apparent, in case of printed advertisement well readable, invitation to carefully read the instructions for use of the medical device and in vitro diagnostic medical device and information pertaining to its safe use, where another legal regulation requires that this be attached to the medical device and in vitro diagnostic medical device.

(4) Advertising for a medical device and an in vitro diagnostic medical device targeted at the general public must not

a)
give the impression that consultation with a doctor, a medical procedure or treatment are not necessary, particularly through an offer of distance diagnosis or offer of distance treatment;

b)
suggest that the clinical performance of the medical device and the in vitro diagnostic medical device is guaranteed, better than or adequate to the efficacy of other treatment or performance of another medical device and in vitro diagnostic medical device or that the use of the medical device and the in vitro diagnostic medical device is not associated with any risks;

c)
suggest that by not using the medical device and the in vitro diagnostic medical device the condition of health of the persons may be adversely affected;

d)
be targeted exclusively at persons younger than 15 years of age;

e)
recommend the medical device and in vitro diagnostic medical device with reference to recommendations of scientists, healthcare professionals or persons who are not scientists or healthcare professionals but who, due to their actual or assumed social standing, could support the use of the medical device and in vitro diagnostic medical device;

f)
refer to the conduct of clinical investigations or any other processes that are the condition for the placement of the medical device and in vitro diagnostic medical device onto the market;

g)
suggest that the safety or performance of the medical device and in vitro diagnostic medical device is guaranteed solely by it being of natural origin;

h)
use a description or detailed account of a specific course of a specific case resulting in possibly incorrect self-diagnosis;

i)
point out to possible cure in an inappropriate, exaggerated or misleading manner;

j)
use inappropriate, exaggerated or misleading depictions of changes to the human body caused by a disease or trauma or of the action of the medical device and in vitro diagnostic medical device on the human body or parts thereof;

(5) Where the advertising targeted at the general public is designed as a reminder of the medical device and in vitro diagnostic medical device, it must not use any data other than the trade name of the medical device and in vitro diagnostic medical device and, where applicable, its trademark.

Section 5m

Advertising for medical devices and in vitro diagnostic medical devices targeted at professionals

(1) Advertising for medical devices and in vitro diagnostic medical devices targeted at professionals may be disseminated only via communication media intended primarily for such professionals, particularly through scientific publications, scientific press, professional audio-visual programmes, and it must contain

a)
sufficient, provable, and objective data that allow the professionals to create their own opinion on the clinical benefit of the specific medical device and in vitro diagnostic medical device; data taken over from scientific publications or scientific press must be accurately reproduced and their source must be specified;

b)
basic information contained in the instructions for use of the medical device and in vitro diagnostic medical device to which instructions for use must be attached;

(2) In respect of advertising for medical devices and in vitro diagnostic medical devices targeted at professionals, it is prohibited to offer, promise or provide gifts or any other benefit thereto unless these are of negligible value and related to the professional activities conducted thereby. This shall not apply to the provision of specimen medical devices and in vitro diagnostic medical devices in quantities necessary to try out the medical device and in vitro diagnostic medical device in compliance with its intended purpose of use. Such provided specimen medical devices and in vitro diagnostic medical devices must be visibly labelled as "sample – not for sale" or "free sample".

(3) When sponsoring meetings and scientific congresses as per Section 5k(1)(d) and (e), the refreshments, lodging and transport provided free of charge by the sponsor or organiser must be adequate to the purpose of the meeting, secondary to the purpose of the meeting, and must not apply to persons other than the professionals; in such a case, the prohibition stipulated by paragraph 2 shall not apply to the scope of the provided refreshments, lodging, and transport.

(4) In association with advertising for medical devices and in vitro diagnostic medical devices, professionals must not require or accept benefits prohibited under paragraph 2 or those that are contrary to paragraph 3.

(5) Where the advertising targeted at professionals is designed as a reminder of the medical device and in vitro diagnostic medical device, it must not use any data other than the trade name of the medical device and in vitro diagnostic medical device and, where applicable, its trademark.

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42) 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.

43) Act No 268/2014 Coll., on In Vitro Diagnostic Medical Devices, as amended. Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices, as last amended.

44) Article 21(3) 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.".

5. A new Section 5n shall be added after Section 5m and, including heading, it shall read:

"Section 5n

Advertising for health-targeting products

(1) It is prohibited to advertise for health-targeting products which are not medicinal products or medical devices or in vitro medical devices, suggesting that the product is a medicinal product, medical device or in vitro diagnostic device.

(2) Advertising for products that are not medicinal products, medical devices, in vitro diagnostic medical devices or other products in respect of which this Act stipulates otherwise, must not

a)

suggest that by using the product the health of the person using it will be maintained or improved;

b)
suggest that by not using the product the health of persons may be adversely affected;

c)
recommend the product with reference to the recommendations of scientists, healthcare professionals or persons who are not scientists or healthcare professions but who, due to their actual or assumed social standing, could support the use of the product.".

6. Section 6b(1) sentence three shall be deleted.

7. In Section 7(b), the words ", medical devices and in vitro diagnostic medical devices" shall be added after the words "tissues and cells" and at the end of the text under the letter, the comma shall be replaced with a semicolon and the words "the State Institute for Drug Control is, furthermore, the authority competent to carry out surveillance over compliance with Art. 7 of Regulation (EU) 2017/745 of the European Parliament and of the Council[42)] to the extent it applies to advertising for medical devices," shall be added.

8. In Section 8(1), the words "or medical devices and in vitro diagnostic medical devices as per Section 5l(2)" shall be added at the end of the text under letter (d).

9. Section 8(1)(i) shall read:

"i)
contrary to Section 5b(1) or Section 5m(1), disseminates advertising for human medicinal products or for medical devices or in vitro diagnostic medical devices targeted at professionals via communication media without these communication media being intended primarily for professionals targeted by the advertising for the given product type;".

10. In Section 8(1), the words "or Section 5m(2)" shall be added at the end of the text under letter (j).

11. In Section 8(1), the semicolon at the end of letter (n) shall be replaced with a full stop, and letter (o) shall be deleted.

12. In Section 8(2)(a) and in Section 8a(2)(a), the words "or Section 3(1)" shall be replaced with the words ", Section 3(1) or Section 5n(1)".

13. In Section 8(2)(b), the words "or Section 5j" shall be replaced with the words ", Section 5j, Section 5k(3), (4), (5), (6), (7) or (8), Section 5l(1), (3), (4) or (5), Section 5m(1) or Section 5n(2) or Regulation (EU) 2017/745 of the European Parliament and of the Council[42)]".

14. In Section 8(3)(d), the words "or 5i" shall be replaced with the words ", Section 5i, Section 5k(3), (4), (5), (6), (7) or (8), Section 5l(1), (3), (4) or (5), Section 5m(1) or Section 5n(2) or Regulation (EU) 2017/745 of the European Parliament and of the Council[42)]".

15. In Section 8(4), the words ""or Section 5m(2)" shall be added after the words "Section 5b(4)", and the words "or Section 5m(3)" shall be added after the words "Section 5b(5)".

16. In Section 8(5)(b), the words "(a), (m) or (o)" shall be replaced with the words "(a) or (m)".

17. In Section 8a(1), the words "or medical devices and in vitro diagnostic medical devices as per Section 5l(2)" shall be added at the end of the text under letter (e).

18. Section 8a(1)(f) shall read:

"f)
contrary to Section 5b(1) or Section 5m(1), disseminates advertising for human medicinal products or for medical devices or in vitro diagnostic medical devices targeted at professionals via communication media without these communication media being intended primarily for professionals targeted by the advertising for the given product type;".

19. In Section 8a(1), the words "or Section 5m(2)" shall be added at the end of the text under letter (h).

20. In Section 8a(1), the comma at the end of letter (q) shall be replaced with a full stop, and letter (r) shall be deleted.

21. In Section 8a(2)(d), the words "5i or Section 5j" shall be replaced with the words ", Section 5i, 5j, Section 5k(3), (4), (5), (6), (7) or (8), Section 5l(1), (3), (4) or (5), Section 5m(1) or Section 5n(2) or Regulation (EU) 2017/745 of the European Parliament and of the Council[42)]".

22. In Section 8a(3)(d), the words "5h or 5i" shall be replaced with the words "Section 5h, 5i, Section 5k(3), (4), (5), (6), (7) or (8), Section 5l(1), (3), (4) or (5), Section 5m(1) or Section 5n(2) or Regulation (EU) 2017/745 of the European Parliament and of the Council[42)]".

23. In Section 8a(4), the words "or Section 5m(2)" shall be added at the end of the text under letter (a).

24. In Section 8a(4), the words "or Section 5m(3)" shall be added at the end of the text under letter (b).

25. In Section 8a(4)(c), the words "human medicinal products" shall be deleted, the words "or Section 5m(2)" shall be added after the words "Section 5b(4)", and the words "or Section 5m(3)" shall be added after the words "Section 5b(5)".

26. In Section 8a(5)(a), the words "(a), (p) or (r)" shall be replaced with the words "(a) or (p)".

Article V

Transitory provision

For the period of six months of the entry into force of this Act, advertising for medical devices and in vitro diagnostic medical devices created or disseminated on the basis of contracts concluded prior to the date of the entry into force of this Act shall be assessed pursuant to Act No 40/1995 Coll., as amended at the time prior to the entry into force hereof.

PART FOUR

TECHNICAL REGULATION

Article VI

This Act has been notified in compliance with Directive (EU) 2015/1535 of the European Parliament and of the Council of 9 September 2015 laying down a procedure for the provision of information in the field of technical regulations and of rules on Information Society services.

PART FIVE

ENTRY INTO FORCE

Article VII

This Act enters into force on 26 May 2021.

Vondráček, in his own hand
Zeman, in his own hand
Babiš, in his own hand