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*Draft*

**ACT**

of …….…..2019,

**amending Act No 378/2007 on pharmaceuticals and on amendments to certain related acts (the Pharmaceuticals Act), as amended, and Act No 48/1997 on public health insurance and on amendments to some related acts, as amended**

Parliament has adopted the following Act of the Czech Republic:

PART ONE

**Amendment to the Pharmaceuticals Act**

Article I

Act No 378/2007 on pharmaceuticals and on amendments to certain related laws (the Pharmaceuticals Act), as amended by Act No 124/2008, Act No 296/2008, Act No 141/2009, Act No 281/2009, Act No 291/2009, Act No 75/2011, Act No 375/2011, Act No 50/2013, Act No 70/2013, Act No 250/2014, Act No 80/2015, Act No 243/2016, Act No 65/2017, Act No 66/2017, Act No 183/2017, Act No 251/2017, Act No 36/2018, Act No 44/2019 and Act No…/2019, is amended as follows:

1. § 11(g) and (h) read:

'g) takes measures in order to ensure availability of medicinal products important for provision of health services and takes measures to support research, development and availability of medicinal products for rare diseases and medicinal products that could be stipulated as such, as well as medicinal products used by children;

h) takes measures in the event of impending or existing insufficiency of a medicinal product important for providing health services in the Czech Republic;'.

1. § 11(q) reads as follows:

'q) takes measures pursuant to § 77c(6)'.

1. In point 10 of § 13(2)(a), the text ‘under conditions stipulated in § 8(6)’ is deleted.
2. Point 11 is added to the end of § 13(2)(a), which reads as follows:

'11. a measure of a general nature pursuant to § 77c(1) permitting distribution of a subsidised medicinal product to a different Member State or third country, and a measure of a general nature pursuant to § 77d restricting or prohibiting the distribution of a medicinal product to a different Member State or third country if a shortage thereof would threaten availability and efficacy of treatment for patients in the Czech Republic with an impact on public health protection'.

1. § 13(3)(q) and (r) read as follows:

'q) within the scope of the eRecept system, provides access to a service pursuant to § 81(1)(h);

r) provides and publishes, in a manner permitting remote access in an open data format, specifications of a communications interface facilitating automated electronic submission and confirmation of orders through an emergency information system for special orders and delivery of a subsidised medicinal product (hereinafter an 'emergency system').'.

1. The following sentence is inserted after the first sentence of § 33(2): 'If marketing of a medicinal product is suspended or terminated, as soon as it receives this information the Institute will publish it on its website along with information whether this medicinal product is directly replaceable by a different medicinal product, and if so, which one.', and the following sentences are added after the fourth sentence: 'If notified information specified in sentence one to three changes, including the reasons for suspension or termination, including the expected duration of suspension, the marketing authorisation holder must immediately inform the Institute or the Veterinary Institute of this fact. Suspension of marketing of a medicinal product that is subsidised by public health insurance when issued on prescription (hereinafter a 'subsidised medicinal product') that the Institute has not identified as being replaceable must last no more than 120 days during the past 12 months'.
2. § 33(3)(g) reads as follows:

'g) in the case of a medicinal product for human use,

1. establish and operate a publicly accessible professional information service on medicinal products for the one who holds marketing authorisation, and to inform the Institute of the address of this service and any changes thereto; the publicly accessible information service must not be used for advertising,51) and the information it provides must be in accordance with all the information about the product; information provided through a publicly accessible information service also includes up-to-date information whether the medicinal product is or is not marketed in the Czech Republic;

2. ensure the qualifications of sales representatives are appropriate to the nature of the medicinal product, ensure that information sales representatives obtain from persons they visit concerning the use of the promoted medicinal products, especially information on all adverse effects is passed on, and verify that sales representatives are fulfilling their obligations pursuant to special legislation;51) and

3. after the medicinal product has been put into circulation, ensure that it is supplied in appropriate quantities and intervals for the needs of patients in the Czech Republic; a marketing authorisation holder must not fulfil this obligation to a significant degree through deliveries in an emergency system pursuant to this Act'.

1. New § 33a to 33c are inserted after § 33 that including their headings read as follows:

'**Emergency system**

§ 33a

(1) The holder of marketing authorisation for a subsidised medicinal product must ensure the establishment and operation of an emergency system if availability of this medicinal product for patients cannot be ensured in a different manner pursuant to this Act. The holder of marketing authorisation for a subsidised medicinal product will ensure operation of the emergency system in the form of automated electronic entry and confirmation of orders through a communications interface published by the Institute pursuant to § 13(3)(r), and in case of an outage, also in non-automated form. The holder of marketing authorisation for a subsidised medicinal product must ensure the emergency system is kept in constant operation.

(2) The holder of marketing authorisation for a subsidised medicinal product must immediately electronically confirm receipt of an order made by a pharmacy through the emergency system, and state the date and time the order was received.

(3) The holder of marketing authorisation for a subsidised medicinal product must, based on an order sent through the emergency system, ensure the subsidised medicinal product for which he holds marketing authorisation is supplied in accordance with this Act to the pharmacy for dispensation to the patient within two workdays of the date the order is received. If the marketing authorisation holder does not have the package size ordered on hand, he will ensure delivery of a different package size of this medicinal product in an appropriate quantity so that the total number of units of the pharmaceutical form of the supplied medicinal product is as close as possible to the prescribed quantity and does not exceed it by more than 50 %.

(4) The holder of marketing authorisation for a subsidised medicinal product is not obliged to ensure delivery of a subsidised medicinal product pursuant to paragraph 3 if the information specified in the order is incorrect.

(5) The holder of marketing authorisation for a subsidised medicinal product or his authorised distributor can use a service established by the Institute pursuant to § 81(1)(h) to verify the existence of the e-prescription through its identifier specified in the order. After entering the e-prescription identifier and the code assigned to the prescribed medicinal product by the Institute the service will send information concerning e-prescription validity and the number of prescribed packages.

(6) The holder of marketing authorisation for a subsidised medicinal product is absolved of the obligation specified in paragraph 3 if he has suspended marketing of the subsidised medicinal product in the Czech Republic and has reported this fact to the Institute in accordance with § 33(2).In addition, the marketing authorisation holder is absolved of the obligation specified in paragraph 3 if he demonstrates that he could not supply the subsidised medicinal product due to a force majeure. The holder of marketing authorisation for a subsidised medicinal product is also absolved of the obligation specified in paragraph (3) if he has terminated marketing the subsidised medicinal product in the Czech Republic and has reported this fact to the Institute in accordance with § 33(2).Grounds for absolution of obligation pursuant to the first or second sentence do not include the case where a marketing authorisation holder or entities making up a group with the marketing authorisation holder give priority to manufacturing or delivering the medicinal product to a market in a different state.

(7) If, for reasons specified in paragraphs 4 or 6, a medicinal product cannot be supplied or the deadline specified in paragraph 3 cannot be met, the holder of marketing authorisation for the subsidised medicinal product must inform the ordering pharmacy of the reasons it cannot be supplied by the day following the date the order was received.

(8) If the holder of marketing authorisation for a subsidised medicinal product arranges delivery of a subsidised medicinal product to a pharmacy through a distributor, he must inform the distributor of the date and time the order placed through the emergency system was delivered.

§ 33b

(1) The holder of marketing authorisation for a subsidised medicinal product must use an electronic form published on the Institute's website to provide a hypertext link to an automated electronic entry and confirmation of orders and information for performing non-automated order entry, and must report changes to this information at least two workdays prior to implementation of the change.

(2) The holder of marketing authorisation for a subsidised medicinal product must use the emergency system to publish a list of distributors he is currently using to ensure delivery of each subsidised medicinal product to patients in the Czech Republic.

(3) The holder of marketing authorisation for a subsidised medicinal product must keep electronic records of distributors and pharmacies for which he has ensured delivery of the medicinal products based on an order made through the emergency system. The records must contain the following information: the distributor, which medicinal product he supplied to a pharmacy, the pharmacy, the supplied medicinal product including the code assigned by the Institute and the batch number, the number of medicinal product packages delivered, and the date the medicinal product was delivered to the pharmacy. He must store this information for five years from the date the medicinal product was delivered to the pharmacy.

(4) The holder of marketing authorisation for a subsidised medicinal product gives the Institute complete and correct information pursuant to paragraph 3 in electronic form. The structure, method, form and frequency of the information are stipulated in implementing legislation.

(5) The holder of marketing authorisation for a subsidised medicinal product that has confirmed an order in the emergency system will inform the Institute of this confirmation within 24 hours through an electronic report that contains the following information on the ordered medicinal product: its name and code assigned by the Institute, number of packages, the pharmacy ID assigned by the Institute, and the date the order was confirmed. The holder of marketing authorisation for a subsidised medicinal product also informs the Institute of cases where, in accordance with § 33a(7), he has not delivered a medicinal product ordered through the emergency system. The holder of marketing authorisation for a subsidised medicinal product submits information pursuant to the second sentence through an electronic report submitted no later than the following workday after the order has been rejected, as follows: the name of the medicinal product and its code assigned by the Institute, the number of packages, the pharmacy ID assigned by the Institute, and the date the order was rejected. The structure, method and form of the report pursuant to the first and second sentence are stipulated in implementing legislation. The Institute stores individual reports, and publishes all reports pursuant to the first sentence for the past calendar month in summary form in a manner permitting remote access.

§ 33c

**Ordering through the emergency system**

(1) if a pharmacy does not have a subsidised medicinal product that is requested by a patient based on an e-prescription in stock, and if the procedure pursuant to § 83(2) cannot be applied nor can the subsidised medicinal product be demonstrably ordered from two distributors listed in the emergency system through which the holder of marketing authorisation for the subsidised medicinal product ensures deliveries for patients in the Czech Republic, or from one distributor if the emergency system lists only one, the operator of this pharmacy can order the prescribed medicinal product via the emergency system of the holder of the marketing authorisation for this medicinal product. If automated electronic ordering and confirmation of orders is not in operation, the operator pursuant to the first sentence can place orders in a non-automated manner.

(2) An order placed through the emergency system must contain the following information: the pharmacy ID assigned by the Institute pursuant to this Act, identification of the ordered medicinal product using the code assigned by the Institute or its name and name supplement, the number of packages of medicinal product ordered, and the e-prescription ID for purposes of verifying the prescription of the ordered medicinal product, including its quantity.

(3) The pharmacy operator must take delivery of a medicinal product based on an order made through the emergency system and issue it only to patients with a prescription.

(4) If a pharmacy operator cannot issue a medicinal product ordered through the emergency system to the patient, he has the right to return it no later than two weeks from its delivery to the distributor who supplied it, unless a longer period of time is agreed upon. The distributor must accept such packaging'.

1. In point 13 of § 77(1)(c), the word 'physicians' is replaced by 'health services providers'.
2. § 77 (1)(h) reads:

h) ensure a sufficient supply of medicinal products for human use to operators authorised to dispense medicinal products in amounts and intervals that correspond to the needs of patients in the Czech Republic; a distributor that ensures delivery of a subsidised medicinal product ordered through the emergency system to a pharmacy must deliver the subsidised medicinal product to the pharmacy that ordered it in a manner so that the pharmacy receives it within two workdays of the date the marketing authorisation holder receives the order; if the pharmacy operator has at least one financial debt with the distributor ensuring delivery of the medicinal product ordered through the emergency system that is more than 30 days past due, delivery is contingent on the price of the medicinal product being paid no later than the moment it is received by the pharmacy operator'.

1. § 77 (1)(q) reads:

'q) proceed in accordance with a measure issued to ensure availability of medicinal products pursuant to § 11(g) or (h), § 77c or pursuant to § 77d;'.

1. § 77c and 77d, including their headings, read as follows:

'§ 77c

**Measures to ensure availability of subsidised medicinal products**

(1) A subsidised medicinal product intended for the market in the Czech Republic can be supplied to a different Member State or third country only by

1. the holder of marketing authorisation for this medicinal product who also holds distribution authorisation; or
2. the distributor of this medicinal product;

and only if this is in accordance with an applicable measure of a general nature that permits the supply of such a medicinal product. The measure of a general nature is issued by the Institute, always as at the fifth day of the calendar month, for all medicinal products that comply with the conditions of paragraph 2, and permits all marketing authorisation holders who also hold distribution authorisation and distributors to supply such medicinal products outside the Czech Republic.

(2) In the measure of a general nature pursuant to paragraph 1, the Institute will specify a list of subsidised medicinal products that have been supplied to pharmacies in the Czech Republic during each of the last three consecutive calendar months, and simultaneously

1. were not ordered by more than five pharmacies during the three last consecutive calendar months through the emergency system;
2. their marketing notified pursuant to § 33(2) was not suspended in any of the last three consecutive calendar months, nor was their marketing, which should have occurred in the period after the measure of a general nature came into effect, suspended, nor does their marketing continue to be under suspension as at the date of issue of the measure of a general nature;
3. they are not listed on the Institute's website pursuant to § 33(2) as medicinal products designated as substitutes for a medicinal product whose marketing has been suspended or that will be suspended pursuant to notification made pursuant to § 33(2) in the period after the measure of a general nature comes into effect;
4. their marketing has not been terminated pursuant to § 33(2), nor has notification been made of a termination of their marketing that is to occur after the measure of a general nature comes into effect; or
5. during the last three consecutive calendar months for which the Institute has reports at its disposal pursuant to § 77(1)(f), were not supplied outside the Czech Republic in quantities greater than 10 % of their average monthly deliveries calculated from the sum of their deliveries to pharmacies in the Czech Republic for the past calendar year.

(3) The Institute will issue the measure of a general nature pursuant to paragraph 1 without proceedings on a draft measure of a general nature, and will notify it with grounds in a public notice on its official bulletin board, solely in a manner permitting remote access.

(4) A measure of a general nature issued pursuant to paragraph 1 takes effect on the date specified therein, but no earlier than the date the public notice is posted.

(5) In exceptional cases, especially when suspension or termination of the marketing of a medicinal product is reported shortly after the measure of a general nature is issued, a new measure of a general nature can be issued on a different date than that specified pursuant to paragraph 1.

(6) In exceptional cases, the Ministry of Health can issue a measure as a decision on administrative proceedings, through which it permits the distribution of a subsidised medicinal product that is not listed in the measure of a general nature pursuant to paragraph 2 outside the Czech Republic, if this is in the urgent interest of an EU Member State due to existing or impending unavailability of such a medicinal product on the market of the given Member State. In doing so, the Ministry of Health takes into account the public interest in protecting public health and ensuring the availability of this medicinal product for patients in the Czech Republic.

§ 77d

**Measures to ensure availability of medicinal products**

(1) If the medicinal product in question is not subsidised, the Institute will issue a measure of a general nature through which it will prohibit or restrict the supply a medicinal product intended for the market in the Czech Republic to a different Member State or to a third country if

1. it finds, especially taking into account information on the availability of medicinal products it has available through its official activity, and information collected from marketing authorisation holders, distributors and pharmacies, that the supply of the medicinal product to a different Member State or to a third country could threaten availability and efficacy of treatment of patients in the Czech Republic with direct impact on public health protection; and
2. the issue of the measure of a general nature is justified by the public interest in protecting public health and in ensuring availability of medicinal products for the needs of patients in the Czech Republic, and it is impossible to issue a different less restrictive measure given the degree of the threat to availability and efficacy of treatment of patients in the Czech Republic.

(2) The Institute will issue the measure of a general nature pursuant to paragraph 1 without proceedings on a draft measure of a general nature, and will notify it with grounds in a public notice on its official bulletin board, solely in a manner permitting remote access.

(3) The measure of a general nature issued pursuant to paragraph 1 is delivered on the date a public notice is posted on the official bulletin board pursuant to paragraph 2.

(4) A measure of a general nature issued pursuant to paragraph 1 takes effect on the date specified therein, but no earlier than the date the public notice is posted.

(5) The Institute will revoke the general measure without delay, through the procedure pursuant to paragraphs 2 to 4, as soon as the reasons for which it was issued cease to exist'.

1. At the end of § 81(1)(f), the word 'and' is replaced by a comma.
2. At the end of § 81(1), the full stop is replaced with the word ‘and’, and (h) is added, which reads:

'h) a service using the entry of an e-prescription identifier and the code assigned to the prescribed medicinal product by the Institute to check the validity of this e-prescription and the number of prescribed packages'.

1. At the end of § 81(3), the full stop is replaced a comma and (n) is added, which reads:

'n) constant access to the service pursuant to paragraph 1(h)'.

1. A new § 81h is inserted after § 81g, which, including its heading, reads as follows:

'§ 81h

**Medicinal products ordered through the emergency system**

(1) If a subsidised medicinal product for a patient is ordered through the emergency system, the pharmacist will use the eRecept [e-Prescription] system to create a record in the central e-prescription database stating that the prescribed medicinal product has been ordered. If a marketing authorisation holder provides information pursuant to § 33a(7) that the ordered medicinal product cannot be delivered, the pharmacist will delete the record he created pursuant to the first sentence.

(2) For the duration of the record pursuant to paragraph 1, the medicinal product so designated cannot be dispensed in a different pharmacy, and the pharmacist must inform the patient of this fact'.

1. In § 82(3)(d), after the text 'from public health insurance', the following text is inserted: 'they must also provide the Institute information in electronic form on medicinal products provided to a different pharmacy in accordance with paragraph 4; the information provided is as follows: identification of the operator authorised for dispensation, identification of the receiving pharmacy, identification of the provided medicinal product and the number of packages provided'.
2. In § 82(3)(j), after the text 'authorised to dispense medicinal products' the text 'pursuant to sentence three of paragraph 2' is inserted.
3. § 82(4) reads as follows:

'(4) If a pharmacy issued medicinal products to inpatient care providers, the inpatient care provider must be specified in the decision issued to such a dispensing pharmacy pursuant to the Health Services Act. If the medicinal products in question are not prepared in the pharmacy, a pharmacy dispensing medicinal products to an inpatient care provider can obtain them from a different pharmacy only in exceptional cases, these being if it does not have a medicinal product in stock and cannot obtain it from the distributor in time, or if another pharmacy has unused supplies of a medicinal product that cannot be returned to the distributor. A medicinal product obtained in this manner can only be issued to an inpatient care provider and used by this provider in providing inpatient care. Such provision and obtaining of medicinal products among health services providers providing pharmaceutical care9) is not considered distribution, and the pharmacy keeps records of this activity to the extent and in the manner stipulated by implementing legislation. A pharmacy that does not dispense medicinal products to an inpatient care provider cannot obtain medicinal products from a different pharmacy. A pharmacy whose operator is simultaneously a marketing authorisation holder must not use medicinal products it has obtained as a pharmacy for distribution. The provisions of sentence two, three and five do not apply to obtaining a medicinal product from a pharmacy operator who is ending pharmacy activities'.

1. § 99(1)(c) and (d) are deleted.

Existing subparagraphs (e) to (o) become (c) to (m).

1. Point 2 of § 99(1)(c) is deleted.

Points 3 to 8 are renumbered 2 to 7.

1. Point 3 of § 99(1)(c) is deleted.

Points 4 to 7 are renumbered 3 to 6.

1. Point 3 of § 99(1)(d) is deleted.

Existing points 4 and 5 are renumbered as points 3 and 4.

1. § 99(1)(f) is deleted.

Existing subparagraphs (g) to (m) are renumbered as (f) to (l).

1. § 99(1)(l) reads:

'l) information about emergency systems of marketing authorisation holders that identifies the marketing authorisation holder who has established and operates the emergency system, a hypertext link to automated electronic entry and confirmation of orders, and information concerning non-automated order entry'.

1. After § 99(1), the following new paragraphs 2 and 3 are inserted:

'(2) The Institute publishes the following on its website in a manner permitting remote access in an open and machine-readable data format:

a) a list of medicinal products broken down by the code assigned by the Institute that pursuant to this Act can be marketed in the Czech Republic, identifying the marketing authorisation holders or parallel import permit holders, specifying the classification of these medicinal products for dispensation or sale pursuant to § 39;

b) summary information on medicinal products marketed in the Czech Republic processed from information reported pursuant to sentence seven of § 33(2), identifying the medicinal product using the code assigned by the Institute, its name and name supplement, without providing the reported price, plus identifying the marketing authorisation holder, and the number of medicinal product packages, specifying whether it was supplied to a distributor or pharmacy or whether it was returned by the distributor or pharmacy;

c) summary information reported pursuant to § 33(2) sentence one and two concerning the start, suspension or termination of marketing of a medicinal product in the Czech Republic;

d) anonymised summary information on medicinal products distributed in the Czech Republic processed from information reported pursuant to § 77(1)(f) concerning medicinal products the distributor distributed to pharmacies, other health care services providers, other distributors, vendors of specified pharmaceuticals, veterinarians and marketing authorisation holders, identifying the distributed medicinal product using the code assigned by the Institute, its name and name supplement, the number of packages, the originator's price and indication to what type of authorised entities the medicinal product was distributed without identifying the distributor who provided the report or the entity to which the medicinal product was distributed;

e) summary information on medicinal products dispensed only on prescription distributed outside the market in the Czech Republic processed from information reported pursuant to § 77(1)(f) concerning medicinal products the distributor distributed to other entities for purpose of distribution or dispensation outside the Czech Republic, identifying the distributor, identifying the distributed medicinal product using the code assigned by the Institute, its name and name supplement, the number of packages, the originator's price and indication to what type of clients the medicinal product was distributed without identifying the entity to which the medicinal product was distributed;

f) anonymised summary information on medicinal products prescribed and dispensed using an e-prescription that is contained in the eRecept system, stating the total number of packages in individual calendar months for each prescribed or dispensed medicinal product, broken down by the district of the healthcare facility in which the medicinal product was prescribed or dispensed;

g) anonymised summary information on dispensed medicinal products processed from information reported pursuant to § 82(3)(d), stating the total number of packages dispensed in individual calendar months for each medicinal product identified by a code assigned by the Institute, its name and name supplement, broken down by dispensation method, and the weighted average of its price taking into account the number of packages in individual calendar months for each dispensed medicinal product;

e) anonymised summary information on medicinal products provided by pharmacies to each other, created from information reported pursuant to § 82(3)(d), concerning medicinal products provided to another pharmacy in accordance with § 82(4), identifying the medicinal product provided using the code assigned by the Institute, its name and name supplement and the number of packages, without identifying the pharmacy that submitted the report or the pharmacy to which the medicinal product was provided;

i) the register of providers pursuant to § 77b, stating their name(s), surname, and business address in the case of an individual, or name and address of their registered office in the case of a corporate entity, the ID number of the broker and reported contact information;

j) the list of distributors pursuant to § 75(3) and distributors pursuant to § 75(4) including their warehouses, stating their name(s), surname, and business address in the case of an individual, or name and address of their registered office in the case of a corporate entity, the ID number of the distributor and reported contact information, and the distributor's qualified individual; and

k) a list of pharmacies and their operators, stating their name(s), surname, and business address in the case of an individual, or name and address of their registered office in the case of a corporate entity, the ID number of the operator, reported contact information and the head pharmacist for each pharmacy, plus information whether the pharmacy also dispenses via mail order or whether the pharmacy provides emergency pharmacy service.

(3) The Veterinary Institute publishes, in a manner permitting remote access, a list of veterinary medicinal products registered in the Czech Republic and the European Union, distinguishing veterinary medicinal products that require a prescription, that do not require a prescription or that are reserved medicinal products, ensuring availability of relevant summary information on the veterinary product and leaflet information, on consumption of veterinary medicinal products by their active ingredient and by method of administration, a list of distributors pursuant to § 75(4), a list of entities pursuant to § 77(5)(a) points 1 to 3, and information on a parallel import permit for a veterinary medicinal product'.

Existing paragraphs 2 to 8 are renumbered as 4 to 10.

1. § 99(4)(a) reads as follows:

'a) information on activity permits and certificates issued, and other information concerning pharmaceuticals and their use, if this information has not been published pursuant to paragraph 1, (2) or (3)'.

1. § 99(4)(e) is deleted.

Existing subparagraphs (f) to (j) become (e) to (i).

1. In § 99(7), the text 'only in the manner pursuant to paragraph 2 or 3 and' is inserted after the text 'provide and publish'.
2. The following sentence is added to the end of § 101(5): 'In a decision on suspending authorisation pursuant to (c), the relevant administrative authority will stipulate the suspension period and the activity that cannot be performed during this time'.
3. The text 'or § 33c(3)' is added to the end of the text in § 103(10(f).
4. § 103(10)(g) reads as follows:

'g) when dispensing medicinal products prescribed electronically, one does not report to the central e-prescription database through the eRecept system pursuant to § 81g(4) that the prescribed medicinal product has been dispensed, nor creates a record in the central e-prescription database through the eRecept system pursuant to § 81h(1) that the prescribed medicinal product has been ordered through an emergency system, nor deletes this record'.

1. At the end of § 103(10)(h), the word ‘or’ is deleted.
2. At the end of § 103(10) the full stop is replaced with a comma, and the following subparagraphs (j) to (n) are added:

'j) orders a medicinal product via the emergency system of a marketing authorisation holder despite failure to fulfil conditions stipulated in § 33c(1);

k) obtains a medicinal product from a different pharmacy contrary to § 82(4);

l) dispenses a medicinal product obtained from a different pharmacy contrary to § 82(4) to an entity that is not an inpatient care provider;

m) provides a medicinal product to a different pharmacy contrary to § 82(4); or

n) fails to provide the Institute information on a medicinal product provided to a different pharmacy pursuant to § 82(3)(d)'.

1. § 105(2)(s) and (t) read as follows:

's) contrary to a measure of a general nature pursuant to § 77d, supplies a medicinal product to a different Member State or third country;

t) does not proceed in accordance with a measure issued by the Ministry of Health to ensure availability of medicinal products pursuant to § 11(g) or (h)'.

1. At the end of § 105(2), the following subparagraphs (u) to (w) are added:

'u) contrary to a measure of a general nature pursuant to § 77c(1), supplies a medicinal product to a different Member State or third country;

v) contrary to § 33c(4), does not accept a subsidised medicinal product returned by a pharmacy he has supplied via an emergency system; or

w) distributes a subsidised medicinal product contrary to a measure pursuant to § 77c(6)'.

1. § 105(5)(j) reads as follows:

'j) fails to ensure the supply of a medicinal product pursuant to point 3 of § 33(3)(g)'.

1. The comma at the end of § 105(5) is replaced by the word '; or' and the following subparagraph (z) is added:

'z) in the case of a subsidised medicinal product that has no substitute, suspends market supply pursuant to § 33(2) for more than 120 days during the past 12 months'.

1. In § 105, the following paragraph 11 is added and reads:

'(11) The holder of marketing authorisation for a subsidised medicinal product commits a misdemeanour by

a) failing to establish or operate an emergency system or failing to keep it in constant operation pursuant to § 33a(1);

b) failing to immediately confirm in writing that an order has been delivered through the emergency system pursuant to § 33a(2);

c) contrary to § 33a(3), failing to ensure a subsidised medicinal product ordered via the emergency system is delivered to a pharmacy;

d) failing to ensure the ordering pharmacy is informed of reasons for non-delivery pursuant to § 33a(7);

e) failing to ensure a distributor is informed of the delivery time and date of an order pursuant to § 33a(8);

f) failing to comply with notification obligations pursuant to § 33b(1);

g) failing to keep electronic records of distributors and pharmacies for which he has ensured delivery of the medicinal products based on an order made through the emergency system pursuant to § 33b(3);

h) failing to give the Institute complete and correct information pursuant to § 33b(4);

i) failing to provide complete and correct information on confirmation of an order pursuant to the first sentence of § 33b(5); or

j) failing to provide complete and correct information on non-delivery of a subsidised medicinal product pursuant to the second sentence of § 33b(5)'.

1. In § 107(1)(b) the text 'or (g)' is replaced by ', (g), (j) or (n)'.
2. In § 107(1)(c), the text '(d), (f) or (i)' is replaced by '(d), (f), (i), (k), (l) or (m)', the text '(t) or (v) is inserted after '(m) to (p)', the text '(x) or (y) or' is replaced by '(x), (y) or (z),' and the text 'or § 105(7), (8), (9) or (10), § 106(3)(d), (e) or (f) or § 106(4)' is replaced by '§ 105(7) to (11), § 106(3)(d), (e) or (f) or § 106(4)'.
3. In § 107(1)(e) the text 'to (t)' is replaced by ', (s), (u) or (w)'.
4. In § 107(2) the text '(t)' is replaced by '(s) or (u)'.
5. In § 114(1), the text '§ 33b(4) and (5) is inserted after the text '§ 33(2),' and 'and § 82(4)' is added to the end of the text of the paragraph.
6. In § 114(2), the text '§ 33(3)(g) point 3,' is deleted.

Article II

**Transitional provisions**

1.The State Institute for Drug Control (hereinafter the 'Institute') will publish specifications on its website for a communications interface pursuant to § 13(3)(r) of Act No 378/2007, as amended effective as of the effective date of this Act, no later than by the end of the second calendar month from the effective date of this Act.

2.An entity that is a marketing authorisation holder for a medicinal product that is subsidised by public health insurance when issued on prescription (hereinafter a 'subsidised medicinal product') as at the effective date of this Act, must provide the Institute information on an emergency information system for special orders and delivery of such a subsidised medicinal product (hereinafter an 'emergency system'), the establishment and operation of which it has ensured pursuant to § 33b(1) of Act No 378/2007, as amended effective as of the effective date of this Act, no later than by the end of the fourth calendar month from the date the Institute published the specifications of the communications interface pursuant to point 1.

3.The Institute will publish information on its website on the emergency systems of marketing authorisation holders pursuant to § 99(1)(l) of Act No 378/2007, as amended effective on the effective date of this Act, within 20 calendar days of the date the marketing authorisation holder fulfilled his obligation pursuant to point 2.

PART TWO

**Amendment to the Act on Public Health Insurance**

Article III

In Act No 48/1997 on public health insurance and amendments to certain related acts, as amended by Act No 242/1997, Act No 2/1998, Act No 127/1998, Act No 225/1999, Act No 363/1999, Act No 18/2000, Act No 132/2000, Act No 155/2000, finding of the Constitutional Court published under No 167/2000, Act No 220/2000, Act No 258/2000, Act No 459/2000, Act No 176/2002, Act No 198/2002, Act No 285/2002, Act No 309/2002, Act No 320/2002, Act No 222/2003, Act No 274/2003, Act No 362/2003, Act No 424/2003, Act No 425/2003 ., Act No 455/2003, Act No 85/2004 ., Act No 359/2004 ., Act No 422/2004 ., Act No 436/2004 ., Act No 438/2004 ., Act No 123/2005, Act No 168/2005 ., Act No 253/2005, Act No 350/2005, Act No 361/2005 ., Act No 47/2006 ., Act No 109/2006., Act No 112/2006., Act No 117/2006 ., Act No 165/2006 ., Act No 189/2006 ., Act No 214/2006 ., Act No 245/2006, , Act No 264/2006, Act No 340/2006, finding of the Constitutional Court published under No 57/2007, Act No 181/2007, Act No 261/2007, Act No 296/2007, Act No 129/2008, Act No 137/2008 ., Act No 270/2008 ., Act No 274/2008 ., Act No 306/2008 ., Act No 59/2009 ., Act No 158/2009, Act No 227/2009 ., Act No 281/2009, Act No 362/2009, Act No 298/2011, Act No 365/2011, Act No 369/2011, Act No 458/2011, Act No 1/2012, Act No 275/2012, Act No 401/2012, Act No. 403/2012, Act No 44/2013, finding of the Constitutional Court published under No 238/2013, Act No 60/2014, Act No 109/2014, Act No 250/2014, Act No 256/2014, Act No 267/2014, Act No 1/2015, Act No 200/2015, Act No 314/2015, Act No 47/2016, Act No 66/2017, Act No 150/2017, Act No 183/2017, Act No 200/2017, finding of the Constitutional Court published under No 231/2017, Act No 290/2017, Act No 282/2018, Act No 45/2019, Act No 111/2019,Act No …/2019 and Act No …/2019, § 39, including its heading, reads as follows:

'§ 39k

**Emergency measures to maintain availability of irreplaceable subsidised medicinal products**

(1) In the case of a medicinal product important for provision of health services where there is impending or existing unavailability, the Institute can issue a decision that will temporarily set or change the maximum price and the amount of and conditions for subsidy for purposes of maintaining the availability of subsidised services for insured individuals (hereinafter 'emergency measure').The Institute can implement an emergency measure if it is in the public interest and if the Ministry of Health has issued a measure or decision pursuant to § 11(a), (h) or (o) of the Pharmaceuticals Act44a) or if the Institute has issued a decision pursuant to § 38 of the Pharmaceuticals Act.

(2) In the case of a medicinal product that has hitherto not been subsidised by health insurance but is basically therapeutically fungible with an unavailable subsidised medicinal product, the Institute will issue an emergency measure setting the maximum manufacturer's price for the medicinal product in the amount of the manufacturer's price for the medicinal product contained in a written arrangement concluded in the public interest pursuant to § 17(2) between the holder of authorisation for marketing or distribution of medicinal products pursuant to the Pharmaceuticals Act and the health insurance company, or, if no such arrangement exists, in the amount of the purchase price of this medicinal product in the state where it can be obtained for purposes of distribution to the Czech Republic. In an emergency measure, the Institute will simultaneously stipulate the amount of the subsidy for the medicinal product so that when taking into account dosage and package size, the difference between the maximum price for the consumer, which for stipulation of the emergency measure is defined as the sum of the manufacturer's maximum price, the maximum mark-up and VAT, and the maximum possible subsidy for a consumer is equal to the difference between the maximum price for the consumer and the maximum possible subsidy for the consumer for the medicinal product whose unavailability led to the emergency measure being issued. The Institute will stipulate the maximum price and the amount of and conditions for a subsidy for a set period, this being the expected period of unavailability of the medicinal product whose unavailability led to the emergency measure being issued, the maximum being one year with no extension possible. The Institute will stipulate conditions for a subsidy pursuant to the subsidy conditions for the medicinal product whose unavailability led to the emergency measure being issued, or if it is in the public interest it will stipulate them so that the medicinal product is subsidised only in the case of indications for which no other available medicinal products can be used.

(3) In the case of a medicinal product that is subsidised by health insurance, the Institute will issue an emergency measure changing the maximum manufacturer's price for the medicinal product in the amount of the manufacturer's price for the medicinal product contained in a written arrangement concluded in the public interest pursuant to § 17(2) between the holder of authorisation for marketing or distribution of medicinal products and the health insurance company, or, if no such arrangement exists, in the amount of the purchase price of this medicinal product in the state where it can be obtained for purposes of distribution to the Czech Republic. The Institute will simultaneously stipulate the amount of the subsidy for the medicinal product so that when taking into account dosage and package size, the difference between the maximum price for the consumer is equal to the difference between the maximum price for the consumer and the maximum possible subsidy for the consumer stipulated for the medicinal product prior to the emergency measure being issued. The Institute will stipulate conditions for a subsidy identical to those stipulated in proceedings pursuant to § 39g, or if it is in the public interest it will stipulate them so that the medicinal product is subsidised only in the case of indications for which no other available medicinal products can be used. The Institute will change the maximum price and the amount of subsidy for a set period, this being the expected period of unavailability of the medicinal product that led to the emergency measure being issued, the maximum being one year with no extension possible. The enforceability of the original decision issued pursuant to § 39h for the medicinal product whose unavailability led to the emergency measure being issued is suspended for the period the emergency measure is enforceable. This does not prevent proceedings from being commenced and conducted, and a decision from being issued on a change in the maximum price or the amount of and conditions for a subsidy of this medicinal product pursuant to § 39i, as well as the performance of an in-depth or shortened check of the reference group to which this medicinal product belongs, including this medicinal product; such a decision can be enforced for this medicinal product only after the enforceability period of the emergency measure expires.

(4) The Institute will issue an emergency measure ex officio or upon request by an entity specified in § 39f(2) or an entity that is authorised to distribute medicinal products. The request must contain information pursuant to § 39f(5)(a) to (e), (h) and (i), § 39f(6)(b), a copy of the measure or decision pursuant to the Pharmaceuticals Act specified in paragraph 1, and proof of the purchase price or a written arrangement pursuant to paragraph 2 or (3).Participants in the proceedings are the applicant and entities specified in § 39f(2).

(5) While the emergency measure pursuant to paragraph 2 or (3) is in force, the Institute will decide on early termination of such an emergency measure if it is in the public interest, especially if the unavailability of subsidised services for insured individuals is no longer impending or no longer exists.

(6) If the request has all the prescribed particulars and has no defects, the Institute will notify all participants it is aware of and simultaneously will ask them to comment on the supporting documentation for the issue of an emergency measure pursuant to paragraph 2 or (3) or a decision pursuant to paragraph 5.In ex officio proceedings, the Institute will ask participants to comment on the supporting documentation for the issue of an emergency measure pursuant to paragraph 2 or (3) or a decision pursuant to paragraph 5 simultaneously with the notification of commencement of proceedings. Participants in the proceedings have the right to comment on the supporting documentation for a period of five days; the Institute can rule to extend this period. In proceedings pursuant to the first sentence, all written materials are delivered pursuant to § 39o.An emergency measure pursuant to paragraphs 2 and 3 and a decision pursuant to paragraph 5 is enforceable upon issue of the next list pursuant to § 39n(1); § 39h(3) is not applied.

(7) An emergency measure pursuant to paragraph 2 or 3 and a decision pursuant to paragraph (5) can be appealed. The appeal deadline is five days from the date the emergency measure is delivered. Appeals against emergency measures pursuant to paragraphs 2 and 3 and against decisions pursuant to paragraph 5 do not have suspensory effect. If an emergency measure or decision pursuant to the first sentence is appealed, it is provisionally enforceable pursuant to paragraph 6 mutatis mutandis.

(8) The Institute will immediately inform the Ministry of Health of emergency measures issued pursuant to paragraphs 2 and 3 and of decisions pursuant to paragraph 5'.

PART THREE

**Technical regulation**

Article IV

This Act was notified in accordance 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 FOUR

**EFFECTIVE DATE**

Article V

This Act comes into effect on ………………, with the exception of Article I point 8, which comes into effect on the first day of the sixth calendar month following its promulgation.