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LAWS AND REGULATIONS

PROMULGATED TO GIVE EFFECT TO THE PROVISIONS OF THE INTERNATIONAL TREATIES ON NARCOTIC DRUGS AND PSYCHOTROPIC SUBSTANCES

In accordance with the relevant articles of the international treaties on narcotic drugs and psychotropic substances, the Secretary-General has the honour to communicate the following legislative texts

CZECH REPUBLIC

Communicated by the Government of the Czech Republic

NOTE BY THE SECRETARIAT

(a) Some editing of texts may be done by the Secretariat in the interest of clarity. In this connection, words in square brackets [ ] have been added or changed by the Secretariat.

(b) Only passages directly relevant to the control of narcotic drugs or psychotropic substances have been reproduced in this document. Non-relevant parts of laws and regulations have been deleted by the Secretariat; such deletions are indicated by [...].

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*Note by the Secretariat: This document is a direct reproduction of the texts communicated to the Secretariat.

E/NL.2001/60

Gazette Law No. 167/1998 on Dependency Producing substances and on Amendment of Some Other Acts

The Parliament has approved the following Gazette Law of the Czech Republic

PART I

Chapter I

INTRODUCTORY PROVISIONS

Section I
Scope of the Gazette Law

(1) This Gazette Law governs

a) ways of handling dependency producing substances, preparations containing dependency producing substances(hereinafter referred to as „preparations"), some substances used in manufacture or transformation of dependency producing substances (hereinafter referred to as „precursors") and the handling essential chemicals, import, export and transit operations related therewith[1].
b) cultivation of poppy, cannabis, and coca, import and export of poppy straw.

(2) This Gazette Law shall not govern handling of precursors contained in:
a) pharmaceuticals in the form of medicaments[2]
b) other products or substances should the composition of such products and substances be such that the precursors contained in them cannot be used or recovered by readily applicable methods.

Section 2
Definitions

The following definitions apply throughout this Gazette Law:
a) „dependency producing substances" means narcotic drugs and psychotropic substances in Schedule 1 to 7 annexed to this Gazette Law[1],

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[1] Section 139, paragraph 8, Act No.13/1993 Coll. of the Czech National Council, Customs Act in terms of Act No. 113/1997.

[2] Section 2, paragraph 3, Act No. 79/1997 Coll., upon Pharmaceuticals and Modifications and Amendments to some Related Acts.

[1] Note by the Secretariat: The schedules annexed to this law are respectively identical to: **Schedule 1**: Schedule I of the Single Convention on Narcotic Drugs; 1961, **Schedule 2**: Schedule II of the Single Convention on Narcotic Drugs, 1961, **Schedule 3:** Schedule IV of the Single Convention on Narcotic Drugs, 1961, **Schedule 4:** Schedule I of the Convention on Psychotropic Substances, 1971, **Schedule 5:** Schedule II of the Convention on Psychotropic Substances, 1971, **Schedule 6:** Schedule III of the Convention on Psychotropic Substances, 1971, **Schedule 7:** Schedule IV of Convention on Psychotropic Substances, 1971. They are therefore not reproduced here and can be consulted with the Secretariat.

b) „preparation“ means any solution or mixture, in whatever physical state, containing one or more dependency producing substances,
c) „precursor“ means any substance in Schedule 9[2] including any solution or mixture in whatever physical state, containing one or more substances in Schedule 9, except for the substances indicated in Section 1, paragraph 2, this Gazette Law,
d) „essential chemical“ means any substance in Schedule 10[3] annexed to this Gazette Law,
e) „poppy straw“ means all overground parts (except for seeds) of poppy (Papaver somniferum) including their crushed form,
f) „cannabis“ means a flowering or fruit-tops of the cannabis plant (excluding the seeds)or any overground part of any plant of Cannabis genus which has a top.

Chapter II
Handling dependency producing substances, preparations, precursors and essential chemicals

Section 3
Handling dependency producing substances, preparations and precursors

(1) Handling dependency producing substances, preparations and precursors means:
a) research, manufacture, transformation, purchase, storage, delivery and use of dependency producing substances, preparations and precursors,
b) purchase and sale of dependency producing substances, preparations and precursors including acquisition and disposition of any other rights related to such substances or other obligations related thereto, mediation of such agreements and representation for the purpose of conclusion of such agreements.

(2) Dependency producing substances in Schedules 3 or 4, and preparations containing such substances can be used solely for scientific and very limited medical purposes defined in the relevant handling permit. Other dependency producing substances and preparations containing such dependency producing substances can be used solely for medical, scientific, teaching or veterinary purposes.

Section 4
Handling permit

A handling permit is needed in order to be able to handle dependency producing substances, preparations and precursors, unless otherwise provided herein.

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[2] Note by the Secretariat: Schedule 9 annexed to this law is identical to Table I to the United Nations Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances, 1988. It is therefore not reproduced here and can be consulted with the Secretariat.

[3] Note by the Secretariat: Schedule 10 annexed to this law is identical to Table II to the United Nations Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances, 1988. It is therefore not reproduced here and can be consulted with the Secretariat.

Section 5
Handling dependency producing substances and preparations without a handling permit

(1) Dependency producing substances in Schedules 1, 2, 5, 6 or 7, and preparations containing such substances shall not subject to a handling permit in the event that:
a) they are acquired, disposed of and stored by pharmacists solely for the purpose of pharmacy operations,
b) they are destroyed by persons authorized thereto pursuant to a special act[3].

(2) Preparations containing dependency producing substance in Schedules 1, 2, 5, 6 or 7, can be handled without a handling permit
a) solely by persons operating health facilities or social care institutions who can acquire, dispose of and store such substances solely for the purpose of dispensing health services,
b) solely by natural and legal persons authorized to perform the veterinary profession activities who can acquire, dispose of and store such substances solely for the purpose of provision of professional veterinary activities,
c) by medical doctors who can prescribe them when providing health care in health facilities and social care institutions
d) by medical doctors and other health professionals in hospitals and out-patient health facilities and social care institutions for medical purposes,
e) by veterinary surgeons who can prescribe them and use for the purpose of veterinary care[4],
f) by pharmacists in pharmacies who can prepare and dispense substances according to a prescription form (hereinafter only „prescription“) or according to a order form (hereinafter only „order“),
g) by pharmacists or pharmaceutical technicians under pharmacists' supervision who can receive such substances and transform them into medical preparation forms,
h) by natural persons who can acquire such substances, even by proxies, based on a prescription issued by a medical doctor, then store them and use them according to the prescription for the personal use of natural persons,
i) by natural and legal persons who can acquire them, even by proxies, based on a prescription issued by a veterinary doctor or who can acquire them from natural or legal persons authorized to conduct veterinary activities, store them and use them according to the issued prescription or the set diagnosis for the purpose of veterinary care.
j) acquired, disposed, warehoused, transported and used by those commissioning and those performing tests in clinical assessment of humane medicaments pursuant to a special Act[5].

(3) No handling permit shall be required for the purpose of transportation of dependency producing substances, preparations and precursors performed in favour of a person who is authorized to handle dependency producing substances, preparations and precursors.

(4) Without a handling permit it is possible to transport limited quantities of preparations containing dependency producing substances in Schedules 2, 6 or 7 in the transport means destined for international transportation for the purpose of first-aid kits and emergency.

(5) No handling permit shall be required in order to acquire, store and transform cannabis for industrial purposes (for fibres and seeds) and for experiment purposes including trade with cannabis for such purposes.
(6) No handling permit shall be required for the activities of the state bodies conducted within the scope of their competencies; for the activities of local government bodies within the scope of their competencies delegated to them by the central government and for the purpose of local public order affairs pertaining to the scope of

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[3]Act No. 125/1997 Coll. on Waste

[4]Section 25, paragraph 1., subparagraph a), of Act No. 87/1987 Coll. upon Veterinary Care in terms of Act No. 437/1991 Coll., Act No. 79/1997 Coll. and Act No. 110/1997 Coll.

[5] Section 33 and subsequent Sections of Act No. 79/1997 Coll.

their powers; and for the activities of Czech Army and the Police of the Czech Republic (while fulfilling) of the tasks assigned to them.

Section 6
Handling precursors without a handling permit

(1) Precursors can be handled without a handling permit:
a) by pharmacists who can acquire, dispose of, transform and store them only for the purpose of pharmacy operations,
b) by pharmacists or pharmaceutical technicians under supervision of pharmacists who can receive them and transform them into medicaments,
c) by persons authorized to destroy them pursuant to a special act[6].

(2) No handling permit shall be required for the activities of the state bodies conducted within the scope of their competencies; for the activities of local government bodies within the scope of their competencies delegated to them by the central government and for the purpose of local public order affairs pertaining to the scope of their powers; and for the activities of Czech Army and the Police of the Czech Republic (while fulfilling) of the tasks assigned to them.

Section 7

The Ministry of Health can specify, by a decree, other cases when no handling permit shall be required for the purpose of handling dependency producing substances, preparations and precursors.

Section 8
Issuance of the handling permit

(1) The handling permit hereunder shall be issued by the Ministry of Health. There is not legal entitlement to obtain such handling permit.

(2) The handling permit shall give the authorization to conduct solely the activities specified therein and in case of a manufacture handling permit the handling permit may specify the maximum admissible volume of the manufactured dependency producing substances, preparations or precursors. Any modifications to the authorized activities or their extension can be done solely based on a new handling permit. The existing handling permit shall cease to be valid upon issuance of a new handling permit.

(3) The handling permit shall be issued for a period of one year.

(4) The handling permit shall not be transferable.

(5) The handling permit can be issued solely to an natural person who meets the criteria of blamelessness, permanent residence in the Czech Republic or to legal persons in the Czech Republic which can prove the blamelessness of natural persons registered in the Commercial Register who are authorized to act on behalf of the given company; legal persons which are not subject to registration in the Commercial Register shall prove the integrity of natural persons who are identified in the foundation documents as persons authorized to act on behalf of the entity. The integrity for the purpose hereof shall mean that the person has not been condemned by a final judgement for having committed an intentional criminal offence or a negligence offence committed in relation with handling dependency producing substances, precursors and pharmaceuticals. The integrity shall be proved by a criminal record extract which cannot be older than three months.

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[6] Act Nº 125/1997 Coll. on Waste.

(6) The handling permit can be issued solely to legal persons or natural persons who have appointed an authorized person. This requirement shall not apply in the event that the natural person - entrepreneur can prove that he/she meets the requirements imposed upon the authorized persons hereunder.

(7) The application for the handling permit must be submitted on the form issued by the Ministry of Health. Should the application relate to manufacture of dependency producing substances, preparations and precursors indicated Schedule 9, the technological prescriptions of the envisaged manufacture must be enclosed.

(8) In case of violations of the obligations arising from this Gazette Law or from the decision issued based on this Gazette Law and in case of false or incomplete information provided in the application form for the handling permit, the Ministry of Health can decide to withdraw the handling permit.

Section 9
Authorized person

(1) Any person who handles dependency producing substances, preparations and precursors based on a handling permit must appoint an authorized person for the whole validity of the handling permit unless the handling permit exempts the obligation to appoint such authorized person pursuant to Section 8, paragraph 6, the second sentence hereof.

(2) The authorized person shall be responsible for:
a) keeping the records and documentation prescribed by this Gazette Law,
b) perform the notification duties prescribed by this Gazette Law.

(3) As an authorized person may be appointed a Czech citizen having his/her permanent residence in the Czech Republic and who meets the general, health, and professional requirements to handle dependency producing substances set up by this Gazette Law. The health capacity shall be proved by an the authorized person (affidavit).

(4) As an authorized person may be either a person employed based on a full time labour contract agreed for given working time or a partner to a general partnership, or general partner of a limited partnership acting secretary of a limited liability company, a member of the board of directors of a joint-stock company or a co-operative a member of a board of a non-profit organization or an agent acting per procurationem.

(5) Internal regulations issued by the person that is obliged to appoint an authorized person must make sure that the activities regulated by the handling permit shall be performed only with the consent of such authorized person.

(6) The authorized person shall co-sign:
a) the application for the handling permit
b) the application for the export or import authorization
c) reports given in terms of the notification duty by this Gazette Law.

(7) The authorization person who is not an employee can renounce to fulfil his/her function by a written notice given to the natural or legal person for which he/she exercises the authorized person's functions.

(8) Should the authorized person or another person performing his/her functions pursuant to article 8, paragraph 6, be temporarily unable to perform this function, the handling permit holder shall immediately appoint another person substituting the authorized person. The appointment of the substitute and termination of his/her appointment must be notified in writing to the Ministry of Health without any delay. The substitute must meet all the requirements of the general, health and professional capacity of the authorized person set forth hereunder.

(9) Should the authorized person cease to meet the imposed requirements or should the authorized person, for any reasons whatsoever, be permanently unable to perform his/her function or should the authorized person renounce to his/her function, the handling permit holder shall appoint a new authorized person within thirty days and ask the Ministry of Health to change the handling permit accordingly. The application for modification of the handling permit shall be made on the relevant form issued by the Ministry of Health and shall be co-signed by the newly appointed authorized person.

Section 10
Storage

(1) Dependency producing substances, preparations and precursors shall be stored in locked rooms the walls, ceilings and floors of which have been made from materials preventing access to the stored substances or in stationary metal boxes equipped with locks.

(2) The keys of the rooms used for storage of dependency producing substances, preparations and precursors can be issued only to the entitled persons and must be kept separately from keys of the other rooms in the building.

(3) The stored dependency producing substances, preparations and precursors including the equipment for their manufacture must be protected against loss, theft and abuse, whilst this protection shall include measures such as permanent physical protection and suitable technical means (such as fences, electronic security systems etc.)

(4) The above mentioned duties shall not be mandatory in case of the storage which is not subject to a handling permit. In health care facilities, in social care institutions and in the premises of persons authorized to provide veterinary care, dependency producing substances in Schedule 1 or 5, and preparations must be stored in stationary metal boxes equipped with locks.

Section 11
Transportation

(1) Dependency producing substances in Schedules 1, 3, 4 or 5, preparations and precursors can be transported solely in metal containers equipped with locks or in specially designed travelling cases equipped with a locking mechanism or in a closed space of means of transport that have been adapted in a manner preventing leakage of such substances outside the closed space. While loading, carrying and unloading such substances, the shipment company shall provide for permanent guarding. The transporting routes must be changed on an irregular basis and must not be published.

(2) Dependency producing substances in Schedules 1, 2, 4 or 5, preparations and precursors shall be labelled, while carried, in such a way that would enable to identify them whilst the marking must be done in a way that would prevent any unauthorized persons to find out what is carried.

Section 12

Trade

Dependency producing substances, preparations and precursors can be sold solely to persons who are authorised to handle such them. The same shall apply to transfers of other rights relating to dependency producing substances, preparations and precursors.

Section 13
Dispensation of pharmaceuticals

(1) Pharmaceuticals[7] containing dependency producing substances can be dispensed in a pharmacy to a person without a permit solely based on a prescription or a order; in case of medicinal preparations containing dependency producing substances in Schedules 1 and 5, the prescription or the order must be marked by a blue stripe going from the left bottom corner towards the right top corner.

(2) Prescriptions or orders marked by a such blue stripe shall be made on the relevant printed forms which shall be subject to strict accounting rules and which shall be issued only by the District Offices exclusively to the proper hands of entitled natural persons.

(3) Medicinal preparations containing dependency producing substances cannot be dispensed repeatedly based on one prescription.

Section 14
Destruction of waste and surplus and unfit-for-use dependency producing substances, preparations and precursors

(1) Unfit-for-use dependency producing substances, preparations and precursors including waste containing them must be destroyed.

(2) Destruction of unfit-for-use dependency producing substances, preparations and precursors including waste containing them which belong to pharmaceuticals pursuant to a special act[8] shall be governed by regulations relating to pharmaceuticals.

(3) Destruction of unfit-for-use dependency producing substances, preparations and precursors including waste containing them which do not belong to pharmaceuticals pursuant to a special act[9] can be done only at presence of a district office representative. The person performing destruction shall draw a report, which shall be signed by the present district office representative.

Section 15
Prohibitions

It shall be prohibited:

a) to place dependency producing substances, preparations and precursors in customs warehouses, free zones and free customs warehouses[10]
b) to send dependency producing substances, preparations and precursors
   1. by mail as ordinary mail deliveries
   2. through mail boxes, or

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[7] Section 2, paragraph 1 of Act No. 79/1997 Coll. on Pharmaceuticals and modifications and amendments to related legislation.

[8] Act Nº 125/1997 Coll. on Waste.

[9] See 8)

[10] Sections 162, 162a and 220, of Act No. 13/1993 Coll. of the Czech National Council in terms of Act No.113/1997 Coll.

3. to persons who are not authorised to handle dependency producing substances.

c) to hand over to another person, in whatsoever manner, mushrooms of Psilocybe genus,
d) to obtain opium from Papaver somniferum
e) to obtain Cannabis resin and tetrahydrocanabinols from Cannabis plant (genus Cannabis)
f) to advertise dependency producing substances, preparations and precursors.

Section 16
Register of manufacturers of essential chemicals

In order to combat any unauthorized manufacture of dependency producing substances, persons who intend to manufacture essential chemicals, on an ad hoc basis or permanently, shall be obliged to register themselves with the Ministry of Health prior to commencement thereof. The application for registration shall be submitted on the relevant form issued by the Ministry of Health for that purpose.

Chapter III
Capacity to handle dependency producing substances, preparations and precursors

Section 17
General capacity

(1) The activities for which a handling permit is required and the activities stated in Section 5, paragraph 1, subparagraph a), paragraph 2, subparagraphs a) and b) and paragraph 6 and in Section 6, paragraph 1, subparagraph a) and paragraph 2 and the activities involving a direct contact with dependency producing substances, preparations and precursors can be performed solely by physical persons fulfilling the criteria of integrity, legal capacity and minimum age of 18 years. Blamelessness shall be proved by the Criminal Record extract not older than three months.

(2) The criteria stated in paragraph 1 must be met also by natural persons who manage directly the conduct of the activities stated in paragraph 1.

Section 18
Health capacity

(1) The activities for which a handling permit is required and the activities stated in Section 5, paragraph 1, subparagraph a), paragraph 2, subparagraphs a) to g) and paragraph 6 and in Section 6, paragraph 1, subparagraph a) and in paragraph 2 and the activities involving a direct contact with dependency producing substances, preparations and precursors cannot be performed by natural persons whose body contains an dependency producing substances, unless such substance is present due to a treatment prescribed by a medical doctor.

(2) The criteria stated in paragraph 1 must be met also by natural persons who manage directly the conduct of the activities stated in paragraph 1.

(3) Employees of persons who perform the activities stated in paragraphs 1 and 2 shall be obliged, upon request of an employer to undergo a medical examination in order to detect presence of an dependency producing substances in their body.

Section 19
Professional capacity

(1) As an authorized person may be appointed a natural person having a university degree from pharmaceutical, medical or veterinary studies, chemical – technological or another similar comparable discipline.

(2) Anyone who performs the activities for which a handling permit is required including the activities stated in Section 5, paragraph 1, subparagraph a) and paragraph 2, subparagraphs a) and b) and in Section 6, paragraph 1, subparagraph a) and the activities involving a direct contact with dependency producing substances, preparations and precursors shall be obliged to make sure that the natural persons who get into direct contact with dependency producing substances, preparations and precursors or who manage directly such activities are properly trained in the nature and effects of such substances and in the ways how to handle them.

Chapter IV
Export, import and transit operations

Section 20
Export

(1) Every individual export of dependency producing substances, preparations, precursors and essential chemicals shall require an authorization issued by the Ministry of Health (hereinafter referred to as „export authorization"). This authorization shall not substitute the export licence pursuant to special regulations[11].

(2) No export authorization shall be required:
a) to export pharmaceutical preparations containing dependency producing substances in Schedules 2, 6 or 7, with the proviso that they are exported by a medical doctor for the purpose of first aid or by a veterinary doctor for the purpose of emergency veterinary care during transportation of animals or by an natural person for personal use whilst the quantity and the type should correspond to the duration of the journey and to the health condition pursuant to the established diagnosis,
b) to export preparations in Schedule 8[4] with the proviso that they are exported by a person who is authorized to handle preparations in Schedule 8,
c) to export a limited quantity of preparations containing dependency producing substances in Schedules 2, 5, 6 or 7, on international means of transport for the purpose of first aid or in cases of emergency,
d) to export mass-produced pharmaceutical preparations containing dependency producing substances in Schedules 1, 2, 5, 6 or 7, with the proviso that they are exported for the needs of health and veterinary services provided by the troops of the Czech Army deployed abroad.
e) to export cannabis for manufacture of fibres and seeds and for experiments.

(3) The Ministry of Health is entitled to adopt a decree and set forth the cases when no export authorization relating to essential chemicals shall be required in the event that the exports of essential chemicals without the appropriate export authorization is permitted by an international treaty binding on the Czech Republic or in the event that the export authorization is not recommended by an international governmental organization dealing with combating illicit manufacture of dependency producing substances and illicit trafficking in them.
(4) An export authorization can be issued only upon submission of an import authorization issued by the

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[11] Act No. 42/1980 Coll. on International Trade in terms of its amendments, Decree No. 560/1991 Coll. on Export and Import Handling permits relating to Goods and Services in terms of its amendments.
Decree No. 560/1991 Coll., on Conditions of Issuance of Export and Import Authorisation of Goods and Services, in the diction of subsequent regulations.

[4] Note by the Secretariat: Schedule 8 annexed to this law is identical to Schedule III to the Single Convention on Narcotic Drugs, 1961. It is therefore not reproduced here and can be consulted with the Secretariat.

importing country or upon a consent of the competent body of the importing country in the event that this country does not require any import authorization.

(5) One copy of the export authorization shall be sent by the Ministry of Health to the competent body of the importing country.

(6) One copy of the export authorization shall be sent to the customs office that is competent to decide to release the goods in the consignment. The customs office shall indicate the data relating to the goods in the consignment. The border customs office shall indicate the date and time of exports of the goods in the consignment send abroad and shall send it to the Ministry of Health.

Section 21
Import

(1) Every individual import of dependency producing substances, preparations and precursors requires an authorization issued by the Ministry of Health (hereinafter referred to as „import authorization"). This authorization does not substitute the import licence issued pursuant to special regulations[12].

(2) No import authorization shall be required:
a) to import mass-produced pharmaceutical preparations containing dependency producing substances in Schedules 2, 6 or 7, with the proviso that they are imported by a medical doctor for the purpose of first aid or by a veterinary doctor for the purpose of emergency veterinary care during transportation of animals or by an natural for personal use whilst the quantity and the type should correspond to the duration of the journey and to the health condition pursuant to the established diagnosis,
b) to import preparations in Schedule 8, with the proviso that they are imported by a person who is authorized to handle the preparations in Schedule 8,
c) to import a limited quantity of preparations containing dependency producing substances in Schedules 2, 5, 6 or 7, on international means of transport for the purpose of first aid or in cases of emergency,
d) to import cannabis for manufacture of fibres and seeds or for experiments.

(3) One copy of the import authorization shall be delivered to the border customs office that is competent to decide to release the goods in the consignment to the transit regime. The customs office shall indicate the date and time when the goods in the consignment were imported. The customs office that is competent to decide to release the goods in the consignment shall indicate, on the copy of the import authorization, the information relating to the goods in the consignment and the date of the release and shall send it to the Ministry of Health.

(4) Upon completion of the import operation, the Ministry of Health shall return the export authorization back to the country which has issued it after having indicated the actual quantity of imported dependency producing substances, preparations, precursors or essential chemicals.

Section 22
Common provisions on export and import

(1) There is no right to obtain an export or import authorization. The export or import authorization shall not be transferable and shall not be transferred to the legal successor.

(2) The application for an export or import authorization shall be made on the relevant form issued by the Ministry of Health for that purpose.

(3) The import authorization shall be issued for a period of six loths. The validity of the export authorization shall

[12] See 10).

be set by the Ministry of Health which shall take into account the duration of the import authorization issued by the importing country. Should the given import or export operation fail to be completed within the set period of time, the person who obtained the export or import authorization shall notify in writing and without any delay the Ministry of Health and shall return to the Ministry of Health all the copies of the export or import authorization which the person holds. The Ministry of Health shall return the export authorization to the issuing country while indicating that the imports were not completed or shall notify thereof the country to which the exports were authorized by the Ministry of Health.

(4) Both in case of import and export, the consignment shall be accompanied by the relevant export authorization unless the export authorization is not required according to the laws of the country of origin of the consignment or unless another administrative procedure applies. Should this obligation fail to be respected, the consignment shall be seized[13] or withdrawn[14].

(5) The Ministry of Health can decide to with the export authorization or import authorization if there are reasonable grounds to believe that the obligations arising from this Gazette Law or from a decision taken pursuant to this Gazette Law have been violated or that this is illicit trafficking under international treaties binding on the Czech Republic.

Section 23
Transit operations

(1) No transit can be conducted without submission of an export authorization and the consignment must be always accompanied by the relevant export authorization unless the export authorization is required according to the laws of the country of origin of the consignment or unless another administrative procedure applies. Should this obligation be not respected, the consignment shall be seized[15] or withdrawn[16].

(2) During the transport, the consignment cannot be unloaded from the mean of transport that carries the consignment.

(3) The obligations set in paragraphs 2 and 3 need not be respected in the event of transit by aircraft if the aircraft does not land in the Czech territory.

Chapter V
Cultivation of cannabis and coca and export and import of poppy straw

Section 24
Cultivation of cannabis and coca

It shall be prohibited
a) to cultivate such types and varieties of cannabis which may contain more than 0,3% of tetrahydrocanabinol substances,
b) to cultivate plants of Erythroxylon genus (coca bush).

Section 25

[13] Sections 309 to 311 of the Act of the Czech National Council No. 13/1993 Coll. in terms of Act No. 113/1997 Coll.
[14] Act of the Czech National Council No. 283(1991 Coll. on the Police of the Czech Republic in terms of Act No. 26/1993 Coll., Act No. 67/1993 Coll., Act No. 163/1993 Coll.
[15] See 13
[16] See 14.

Export and import of poppy straw

(1) A poppy export or import authorization shall be required in order to export or import the poppy straw.

(2) A poppy straw export and import authorization shall be issued by the Ministry of Health which is also authorized to withdraw such authorization if there are reasonable grounds to believe that the obligations arising from this Gazette Law or from a decision issued based on this Gazette Law have been violated or in case of illicit trafficking pursuant to international treaties binding on the Czech Republic. The poppy export authorization can be issued for a period set therein for repeated exports. The issuance and withdrawal of the poppy straw export and import authorizations shall be subject to the provisions of Chapter IV.

Chapter VI
Notification and records

Section 26
Notification obligation pursuant to the handling permit

(1) Persons who are authorized to handle dependency producing substances, preparations and precursors based on a handling permit shall be obliged to transmit to the Ministry of Health:
a) by the end of February, an annual report for the preceding calendar year on manufacture and consumption of dependency producing substances, preparations and precursors, on trade and on status and movement of their stocks,
b) by the end of April, an estimate of manufacture and imports of dependency producing substances, preparations and precursors for the next calendar year,
c) by the fifteenth of the following month, a monthly report on imports and exports of dependency producing substances, preparations and precursors for the preceding quarter.

(2) Upon termination of the activities which require a handling permit, the legal person who was performing such activities shall transmit, not later than one month from termination of such activities, an extraordinary report covering the scope described in paragraph 1, subparagraph a). The same requirement shall apply to the legal successor of a natural person - entrepreneur.

Section 27
Notification obligation of pharmacists

Persons who operate a pharmacy shall submit, by the end of February, to the body that registered the pharmacy, an annual report for the preceding calendar year on the quantities and turnover of the stocks of the dependency producing substances in Schedules 1 or 5 and preparations containing such substances.

Section 28
Notification obligation of essential chemicals manufacturers

Persons registered with the Ministry of Health as manufacturers of essential chemicals (Section 16) shall deliver, by the end of February, to the Ministry of Health an annual report on manufacture of essential chemicals for the preceding calendar year.

Section 29
Notification obligation of persons cultivating poppy and cannabis

Persons cultivating poppy (Papaver somniferum) or cannabis on a total area larger than 100 square meters shall

deliver to the competent territorial department of the Ministry of Agriculture:

a) by the end of December, a report for the preceding calendar year on the area of the land on which the poppy (Papaver somniferum) or cannabis was cultivated and the quantity of the harvested poppy straw,
b) by the end of May, an estimate of the area of the land on which poppy (Papaver somniferum) and cannabis shall be cultivated during the next calendar year.

Section 30
Notification obligation relating to export and import of poppy straw

Anyone who has conducted an export or import of poppy straw shall deliver, by the fifteenth of the first month of the calendar quarter, a quarterly report on exports or imports of such poppy straw for the preceding quarter.

Section 31
Forms of reports

Notifications shall be made on forms issued by the Ministry of Health except for the notifications pursuant to Section 29.

Section 32
Record keeping

(1) Handling dependency producing substances, preparations and precursors including their exports and imports shall be subject to record keeping. Records shall be kept by persons who perform activities which require a handling permit, an export authorization or import authorization, then persons who operate health facilities and persons who operate social care facilities and persons who provide for veterinary care.

(2) Details relating to record keeping shall be set by the Ministry of Health by a decree.

Section 33
Archiving the records

(1) The documentation relating to handling the dependency producing substances and their exports and imports shall be preserved.

(2) The details relating to the ways and duration of archiving shall be set by the Ministry of Health by a decree.

Chapter VII
Inspection

Section 34
Inspectors

(1) Inspection relating to the respect of the obligations arising from this Gazette Law and from decisions issued pursuant to this Gazette Law shall be performed by authorized employees of the Ministry of Health, Ministry of Interior, District Offices and by the district veterinary administrations in case of veterinary care (hereinafter referred to as „inspectors“).

(2) When performing an inspection mission, inspector shall prove their authorization by presenting a badge issued by one of the bodies mentioned in paragraph 1.

(3) Inspector shall be authorized to:
a) enter the site, buildings and rooms,
b) request explanations relating to the established facts and ask for documents,
c) make copies of documents and extracts from them and, if it is not possible to make copies and extracts, to seize documents,
d) take samples to the extent necessary for the inspection purposes.

(4) Upon request of the inspected person, the inspection body shall provide a compensation for the taken samples equal to the production costs or purchase price.

(5) The inspector shall discuss with the inspected person the defects found out during the inspection mission and the ways and deadline of their removal. The inspector shall make a report describing the mission and its results.

(6) The inspected persons shall be obliged to undergo the inspection mission and provide assistance necessary for its completion.

Section 35
Inspection during receipt

Anyone who receives dependency producing substances, preparations and precursors shall verify whether their quantity and type complies with the accompanying documents and notify any serious discrepancies to the Czech Police and the Ministry of Health.

Chapter VIII
Sanctions and seizure of items

Section 36
Sanctions

Sanctions to be imposed shall be fines and forfeiture.

Section 37
Fines

(1) The following fines shall be inflicted to natural person - entrepreneur or legal person:
a) up to the amount of 100 000.-Czech crowns in the event of violations of the obligations relating to record-keeping and documentation pursuant to this Gazette Law,
b) up to the amount of 1 000 000.- Czech crowns in the event of false or incomplete data indicated in the application for the handling permit, in the application for the export authorization or import authorization or when performing the notification obligations hereunder,
c) up to the maximum amount of 10 000 000.- Czech crowns in the event of conducting activities for which a handling permit is required without a handling permit or in the event of exports for which an export authorization is required without the appropriate export authorization or in the event of imports for which an import authorization is required without the appropriate import authorization,

d) up to the maximum amount of 500 000.-Czech crowns in the event of violations of other obligations resulting from this Gazette Law or from a decision issued pursuant to this Gazette Law other than those stated under subparagraphs a) to c).

(2) Fines shall constitute a revenue for the state budget.

(3) When determining the amount of the fine, the gravity of the illegal behaviour and the extent of the actual or imminent prejudice to health and property shall be taken into account.

Section 38
Forfeiture of items

(1) The fine imposed pursuant to Section 37 hereof shall be accompanied by forfeiture of dependency producing substances, preparations, precursors and essential chemicals and the equipment and materials used for manufacture of such items, if they belong to the person to whom the fine has been inflicted and if they have been used or intended to be used for the behaviour constituting a violation of the obligations arising from this Gazette Law or from the decision issued pursuant to this Gazette Law or if they have been obtained through such behaviour or acquired in exchange for an item obtained through such behaviour.

(2) The forfeited item shall be transferred to the possession of the State.

Section 39
The proceedings resulting to imposition of a fine

(1) The fine pursuant to Section 37, paragraph 1, subparagraph a), can be inflicted by the Ministry of Health with respect to the record-keeping and documentation of the activities performed based on a handling permit, in the other cases the fine can be inflicted by a District Office. The fine pursuant to Section 37, paragraph 1, subparagraph b), can be inflicted by the competent District Office in case of violations of the notification obligations by persons operating pharmacies; in the other cases, the fine can be inflicted by the Ministry of Health. The fine pursuant to Section 37, paragraph 1, subparagraph c), can be inflicted by the Ministry of Health. The fine pursuant to Section 37, paragraph 1, subparagraph d), can be inflicted by the competent District Office.

(2) The proceedings resulting in imposition of a fine can be started not later than five years from the behaviour constituting a violation of an obligation set by this Gazette Law or a decision issued pursuant to this Gazette Law or within five years from the day when such illegal situation occurred for the last time.

(3) A fine can be inflicted also when the behaviour constituting a violation of an obligation arising from this Gazette Law or from a decision issued pursuant to this Gazette Law can be sanctioned pursuant to another legal regulation or if such behaviour has been punished pursuant to other legal regulations.

(4) The proceedings resulting in imposition of a fine cannot be started against a person having the immunities and privileges according to international law.

(5) The fine shall be enforced and collected by the competent administrative body that inflicted the fine at the first instance.

Section 40
Seizure of items

(1) Should the forfeiture under Section 38, paragraph 1, hereof fail to be inflicted, it can be decided to seize the item if the item has been used or intended to be used for the behaviour constituting a violation of an obligation arising from this Gazette Law or from a decision issued pursuant to this Gazette Law or if the item has been obtained or acquired through such behaviour and if it does not belong to the person who violated the obligations set by this Gazette Law or a decision issued pursuant to this Gazette Law or if such a person is not the sole owner of such item.

(2) Decision-making concerning the seizure cannot be done in the event that:
a) five years have elapsed from the behaviour having the elements of a violation of the obligations set by this Gazette Law or by a decision issued pursuant to this Gazette Law or five years from the day when such illegal situation occurred for the last time,
b) the item belongs to a person having the privileges and immunities pursuant to the international law.

(3) The seized item shall be transferred to the possession of the State.

Chapter IX
Common, transitory and final provisions

Section 41
Impact on other legal regulations

The provisions of other specific regulations relating to dependency producing substances, preparations, precursors and essential chemicals remain intact[17].

Section 42

All the official and business documents shall use such names of dependency producing substances, preparations and precursors that are stated in the appropriate handling permit, export authorization or import authorization.

Section 43
Co-operation of the state bodies

(1) The central bodies of the state administration shall co-operate with the Ministry of Health during preparation of the documents for the international organizations relating to dependency producing substances, preparations, precursors and essential chemicals within the scope of their competencies pertaining to their authorities.

(2) The district offices shall notify, by the end of February, the Ministry of Health, the data relating to the dependency producing substances, preparations and precursors that were destroyed pursuant to Section 14, paragraph 3 during the preceding year.

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[17] For instance Act No. 79/1997 Coll. on Pharmaceuticals and Modifications and Amendments to some other Related Acts, Act No. 40/1995 Coll. on Regulation of Advertising and on Modifications and Amendments to Act No. 468/1991 Coll. on Radio and TV Broadcasting in terms of the following regulations, Act No. 13/1993 Coll. of the Czech National Council - The Customs Act in terms of Act No. 35/1993 Coll. and Act No. 113/1997 Coll., Act No. 563/1991 Coll. on Accounting in terms of Act No. 117/1994 Coll., Act No. 125/1997 Coll.

(3) The State Institute for Drug Control and the Institute for State Control of Veterinary Biologicals and Medicaments

a) inform regularly to the Ministry of Health on:
   1. received applications to register pharmaceuticals containing dependency producing substances or precursors,
   2. violations of the obligations set by this Gazette Law or a decision issued pursuant to this Gazette Law,
b) deliver, on a regular basis, to the Ministry of Health copies of final decisions on registration of pharmaceutical preparations containing dependency producing substances or precursors,
c) deliver to the Ministry of Health annual reports pursuant to Section 26, paragraph 1, subparagraph a).

Section 44
Application of the provisions on administrative proceedings

(1) Decisions on matters hereunder shall be subject to the general regulations on administrative proceedings[18] except for the registration pursuant to Section 16.

(2) The facts stated in the application for a handling permit, an export authorization, import authorization, a poppy export authorization and a poppy import authorization shall be justified and documented by the applicant in the appropriate manner.

(3) Appeals against decisions on withdrawal of a handling permit, withdrawal of an export authorization, withdrawal of an import authorization, withdrawal of a poppy export authorization and withdrawal of a poppy import authorization shall not have a dilatory effect.

Section 45
Transitory provisions

(1) The handling permit to handle narcotic drugs and psychotropic substances or preparations and the special export or import authorizations relating to narcotic drugs or psychotropic substances or preparations issued pursuant to the hitherto applying regulations shall be considered as handling permits, export authorizations, import authorizations, poppy export authorizations or poppy import authorizations pursuant to this Gazette Law during six months from the effective date hereof.

(2) The proceeding on issuance of a handling permit relating to narcotic drugs and psychotropic substances or preparations and issuance of a special authorization to export or import narcotic drugs or psychotropic substances or preparations pursuant to the regulations[19] which were not finalized on the effective day hereof shall be stopped.

(3) Manufacturers of essential chemicals shall register themselves with the Ministry of Health (Section 16) within three months from the effective day hereof.

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[18] Act No. 71/1967 Coll. on Administrative Proceedings.

[19] Decree of the Government of the Czech Socialist Republic No. 192/1988 Coll. on Poisons and some other Substances Harmful to Health in terms of the Decree of the Government of the Czech Republic No. 182/1990 Coll., Decree of the Government of the Czech Republic No. 33/1992 Coll. and Governmental Decree No. 278/1993 Coll.

PART II

Section 46
Amendments to the Criminal Code

Act No. 140/1961 Coll. - the Criminal Code in terms of Act No. 120/1962 Coll., Act No. 53/1963 Coll., Act No. 56/1965 Coll., Act No. 81/1966 Coll., Act No. 148/1969 Coll., Act No. 45/1973 Coll., Act No. 43/1980 Coll., Statutory Measure No. 10/1989 Coll., Act No. 84/1990 Coll., Act No. 159/1989 Coll., Act No. 47/1990 Coll., Act No. 175/1990 Coll., Act No. 457/1990 Coll., Act No. 545/1990 Coll., Act No. 490/1991 Coll., Act No. 557/1991 Coll., Judgement of the Constitutional Court of the Czech and Slovak Federal Republic from September 4,1992 published in Section No. 93/1992 Coll., Act No. 290/1993 Coll., Act No. 38/1994 Coll., Act No. 91/1994 Coll., Act No. 152/1995 Coll., Judgement of the Constitutional Court No. 110/1997 Coll., shall be amended as follows:

Section 195, including the heading shall read as follows:

Section 195
Common provisions

(1) A special law shall determine what is considered as narcotic drugs, psychotropic substances, preparations containing narcotic drugs or psychotropic substances or as precursors“.

(2) The Government sets up in it Decree what shall considered as poisons in the sense of Section 187, 187 a and 188, and which diseases shall be considered as contagious in the sense of Section 189 to 192 and which elements relate to the poisons of Section 192.

[…]

Section 51
Effective Date

This Gazette Law shall become effective on January 1, 1999.

E/NL.2001/61

DECREE 304
of the Ministry of Health
# of 3rd December 1998

by which the cases when an export authorization for the export of essential chemicals is not required, the details concerning the record-keeping of habit-forming drugs, preparations and precursors and about documenting habit-forming drugs are set down

According to Section 20, paragraph 3, Section 32 paragraph 2 and Section 33, paragraph 2, of law No. 167/1998 Coll., on dependency producing substances and on amendment of some other acts[1] (hereinafter called "law"), the Ministry of Health sets down:

PART ONE
EXPORT OF ESSENTIAL CHEMICALS WIHOUT AN EXPORT AUTHORIZATION

Section 1

For the exporting of the essential chemicals stated in Schedule 10 of the law, no export authorization is required, unless it concerns the export of essential chemicals into the countries stated in Schedule No. 1 of this decree[2].

PART TWO
RECORDS OF DEPENDENCY PRODUCING SUBSTANCES, PREPARATIONS AND PRECURSORS

Section 1
Common provisions about record-keeping

(1) The records concerning the handling, importing and exporting of dependency producing substances, preparations and precursors (hereinafter called "records") must be kept in full, using conclusive evidence in such a way, so that it will truly reflect the facts that are the subject of it.

(2) The dependency producing substances and precursors are identified by the name stated in the relevant Schedule of the law; mass-produced pharmaceuticals[20] are identified only by a registered name[21].

(3) The records are kept in hard-back books with numbered pages (hereinafter called "record book"), unless it is further instituted otherwise. The records are put down in the book on the day when the recorded matter occurred.

(4) Compliance of the records with the actual state is verified by inventory-taking. The inventory is carried out monthly according to the balance on the last day of the calendar month. The performance of the inventory is recorded in the record book, stating the date of inventory, names, surnames, functions and signatures of

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1 Note by the Secretariat: E/NL.2001/60

2 Note by the Secretariat: These schedules where not reproduced here. They can be consulted with the Secretariat.

20 Section 2, paragraph 3 and 11, of Law Nº 79/1997 Coll., about pharmaceuticals and amendments to some related laws.

21 Section 9, paragraph 1, letter a), point 1, and Section 23 of law Nº. 79/1997 Coll.

persons who carried out the inventory. In the record about the performance of the inventory the initial balance of the observed period, total receipt and dispensation and the balance on the day of inventory for all observed items are stated. If any difference between the actual and recorded balance is established, an inventory protocol is made, in which the established differences including their explanation, further names and surnames, functions and signatures of the persons who carried out the inventory are stated.

(5) Corrections of the records are carried out in such a way, so that it will be possible to establish the contents of the original record, and the corrected record is provided with the date and name, surname, function and signature of the person who carried out the correction of the record.

Section 3
Record books

(1) The record book must contain:
a) the business name or designation and the address of the natural person, or the headquarters of the legal person, who carries out the activity about which the record is kept, or as the case may be, the designation of the organizational branch or activity to which the record is related,
b) the names and surnames of the natural persons who enter the records into the record books, their addresses, specimen signatures and the date from which these persons have carried out the records,
c) the date of putting the book into usage as well as the terminating of the usage,
d) the number of pages, with stating the number of the first and the last page,
e) a list of recorded habit-forming drugs, preparations and precursors, with stating the number of pages assigned for the recording of the individual habit-forming drugs, preparations and precursors.

(2) Separate record books may be kept for individual organizational branches.

Section 4
Records kept by means of computer technology

(1) Completed mass-produced pharmaceuticals containing the dependency producing substances stated in Schedules 2, 6 or 7 of the law, may be kept in the records by means of computer technology, as long as:
a) at least once a day a security copy of the data file is made,
b) at least twice a year an archive copy of the data file is made on a write-once storage medium with the manufacturer guaranteed record durability of at least 5 years.

(2) The records kept by means of computer technology must contain:
a) the name of the preparation,
b) the date of receipt or dispensation,
c) the No. of the document about receipt and dispensation
d) the designation of the person or the organizational branch from which the stored preparations were received, or the designation of the person or the organizational branch to which the stocked preparations were dispensed,
e) the amount and the batch of received or dispensed preparations,
f) the inventory balance on the last day of the observed period.

For the purposes of this decree, as the observed period are especially understood the time periods specified for the carrying out of the inventory-taking, the compulsory reports (Section 26 of the law) and the auditing activities (Section 34 of the law).

(3) In case the records are kept according to the paragraphs 1 and 2, they do not have to be kept according to Section 3.

(4) When keeping the records by means of the computer technology, the inventory-taking is carried out according to the balance on the last day of the calendar quarter. An inventory protocols is provided about the carrying out of the inventory, which contains the results of the inventory and the established discrepancies and further the date and names and surnames, functions and signatures of the persons who carried out the inventory-taking.

Section 5
Record keeping in pharmacies

(1) In pharmacies, when handling dependency producing substances, preparations and precursors, for which the handling permit is not required (Sections 5 and 6 of the law), records are kept about the habit-forming drugs listed in Schedules 1 or. 5 of the law, including the preparations that contain them.

(2) The specimen of the page of the record book according to paragraph 1 is established by Schedule 2 of this decree.

(3) Records concerning the handling of the habit-forming drugs, preparations and precursors for which the handling permit is required (Section 4 of the law) are regulated by Section 7 of this decree.

Section 6
Record keeping in other health institutions, welfare institutions and when providing veterinary care

(1) In other health institutions, welfare institutions and when providing veterinary care, when handling the dependency producing substances, preparations and precursors for which the handling permit is not required (Section 4 of the law), records are kept about dependency producing substances listed in Schedules 1 or 5 of the law, including the preparations that contain them.

(2) The lay-out of the page of the record book according to paragraph 1 is established by Schedule 3 of this decree.

(3) Records concerning the handling of dependency producing substances, preparations and precursors for which the handling permit is required (Section 4 of the law) are regulated by Section 7 of this decree.

Section 7
Record keeping during the production, packaging and storing of dependency producing substances, preparations and precursors on the basis of a handling permit

(1) During the production, packaging and storing of the dependency producing substances, preparations and precursors on the basis of a handling permit, records are kept of the dependency producing substances, preparations and precursors:

a) produced,
b) received,
c) stored,
d) taken out of storage,
e) re-worked,

f) used up during the production of other dependency producing substances, preparations or drugs which are not dependency producing substances,
g) stated as losses or wastage anticipated by a technological instruction concerning the production,
h) disposed or handed over for disposal,
i) missing or in surplus with stating the reason.

(2) The specimen of the page of the record book of the production of preparations that dependency producing substances is established by Schedule 4 of this decree.

(3) The specimen of the page of the record book of the storing of dependency producing substances, preparations and precursors for the persons who produce, process or pack the dependency producing substances, preparations and precursors on the basis of a handling permit is established by Schedule 5 of this decree.

Section 8

(1) During the storing of the dependency producing substances, preparations and precursors on the basis of a handling permit, records are kept of the dependency producing substances, preparations and precursors, unless it concerns the procedure according Sections 5, 6 or 7.

(2) The specimen of the page of the record book of the storing of dependency producing substances, preparations and precursors is established by Schedule 5 of this decree.

PART THREE
DOCUMENTATION

Section 9

(1) The Documentation concerning the handling of dependency producing substances, preparations and precursors comprises of:
a) Record books,
b) Data media containing the data of the records kept by means of computer technology,
c) Inventory protocols,
d) Reports about the disposing of the dependency producing substances, preparations, and precursors (section 14 of the law)
e) Protocols about losing or destroying the dependency producing substances, preparations and precursors,
f) Reports about carried out inspections (section 34 of the law)
g) All official decisions including foreign, concerning the handling of the dependency producing substances, preparations and precursors as well as their export and import and further the export and import of poppy straw,
h) Counterparts of reports (sections 26 and 31 of the law),
i) Delivery notes and documents about the acceptance and issuance of the dependency producing substances, preparations and precursors
j) Documents about purchasing, selling or putting out of operation tablet making machine, tablet coating drum and granulating drum.

(2) In pharmacies, beside the documents stated in article 1, copies of prescriptions with a blue stripe as well as copies of order forms with a blue stripe (section 13 paragraph 2 of the law) are to be kept.

(3) In other health institutions or welfare institutions, beside the documents stated in article 1, blocks of used prescriptions[22] marked with a blue stripe as well as blocks of used forms[23] marked with a blue stripe are to be kept.

Section 10
Protocols and reports

When making the statements and reports according to section 9, paragraph 1 letter c), d), e), it is necessary to proceed according to the common provisions for keeping records (section 2). The reports according to section 9, paragraph 1, letter d) and e) must always be confirmed by the responsible person (section 9 of the law).

Section 11
Keeping the documentation

The documentation concerning the handling of the dependency producing substances, preparations and precursors is kept for a period of 5 years from the making of the document, possibly from the last entry in it, according to which of these occurred later.

Section 12
Effective date

This decree shall become effective on January 1, 1999.

[22] Section 3 clause 5 letter b) of decree Nº 343/1997 Coll., by which the method of prescribing pharmaceuticals, requirements of medical prescriptions and rules of their use is set down.
[23] Section 3 clause 6 of decree Nº 343/1997.

E/NL.2001/62

Gazette law 117 of 6 April 2000 whereby the Act No. 167/1998 Coll. on dependency producing substances and on amendment of some other acts[1], in the wording of the Act No. 354/1999 Coll.[2], is amended together with the Act No. 368/1992 Coll. on administrative fees as amended

The Parliament has approved the following Gazette Law of the Czech Republic:

PART ONE
Amendment to the Act on dependency producing substances

Article I

The Act No. 167/1998 Coll. on dependency producing substances and on amendment of some other acts, in the wording of the Act No. 354/1999 Coll., is amended as follows:

1. In Section 1 the wording of paragraph 2, item a), including footnote 2), is as follows:

   "a) pharmaceuticals in the form of medicaments[2a] with the exception of medical drugs containing ephedrine and medical drugs containing more than 30 mg of pseudoephedrine per unit of dosage form,"

2. In Section 1, paragraph 2, item b), the words "used or recovered by readily applicable methods" are replaced by the words "easily used or recovered by means that are easy to utilize".

3. In Section 2, item d), after the words "in Schedule 10", the words "or in Schedule 11" are inserted.

4. In Section 3, paragraph 2, second sentence, the word "or" is replaced by comma and at the end of the sentence the following words are added: "or for other purposes as well, based on the permit issued by the Ministry of Health."

5. In Section 5, paragraph 1, after the words "containing such substances", the words "or the preparations containing ephedrine and pseudoephedrine" are inserted.

6. In Section 5, paragraph 1, item a), after the word "pharmacy", the reference on footnote 2a is inserted, which wording is mentioned below.

7. In Section 5, paragraph 1, item b), after the word "destroyed", the words ", if they are not stored," are inserted.

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[1] Note by the Secretariat:E/NL.2001/60

[2] Note by the Secretariat: This act was not published as it amended the schedules to the law so as to comply to the decisions of the Commission on Narcotic Drugs.

[2a] "Section 16, paragraph 5, Act No. 79/1997 Coll."

8. In Section 5, paragraph 2, after the words "Schedules 1, 2, 5, 6 or 7", the words "and the preparations containing ephedrine and pseudoephedrine" are inserted.

9. In Section 5, paragraph 2, the wording of item f) is as follows:

"f) by pharmacists in pharmacies, who can prepare and dispense such preparations based on the prescription form (hereinafter only "prescription") filled and signed by a medical doctor, or based on the order of natural or legal persons, authorized to provide health care or veterinary care (hereinafter only "order"),"

10. In Section 5, paragraph 2, at the end of item j) the full stop is replaced by comma, and item k) is added, which wording is as follows, including footnote 5a:

"k) acquired, disposed, warehoused, transported and used by those commissioning and those performing tests during the preparation or execution of clinical assessment of veterinary medical drugs pursuant to a special Act[5a]."

11. In Section 5, paragraph 4, after the words "Schedules 2, 6 or 7" the words "and the preparations containing ephedrine and pseudoephedrine" are inserted.

12. In Section 6, paragraph 1, item c), after the words "dispose of", the words ", if they are not stored," are inserted.

13. In Section 8, paragraph 3, the words "one year" are replaced by the words "two years".

14. In Section 8, paragraph 5, the first sentence is replaced by the following sentences: "The handling permit can be issued solely to a natural person, who meets the criteria of blamelessness and permanent residence in the Czech Republic, or to a legal person with the seat in the Czech Republic. The condition of the residence or seat in the Czech Republic does not apply, if the said person is a citizen of EU Member State, a citizen of the Czech Republic with no residence on the territory of the Czech Republic, or a legal person with the seat in EU Member State. The legal person is obliged to prove the blamelessness of the natural persons, who are entered in the Commercial Register as the persons authorized to act on behalf of the legal person; the legal person that does not register with the Commercial Register will prove the blamelessness of the natural persons that are entered in the documents on establishment as the persons authorized to act on behalf of the legal person."

15. In Section 8, paragraph 9 is added, which wording will be as follows:

"(9) If the natural or legal person discontinues the activity, for which the handling permit was issued, it is obliged to announce this fact immediately to the Ministry of Health, which by its decision will cancel the handling permit."

16. In Section 9, paragraph 3 will have the wording as follows:

"(3) A natural person with permanent residence on the territory of the Czech Republic may be appointed as an authorized person. The condition of the residence in the Czech Republic does not apply, if the said person is a citizen of EU Member State or a citizen of the Czech Republic with no residence on the territory of the Czech Republic. This person must meet general, health and professional requirements to handle dependency producing substances."

[5a] "Section 39, Act No. 79/1997 Coll."

17. In Section 9, after paragraph 3 a new paragraph 4 is inserted, which wording is as follows:

"(4) The eligibility of the authorized person with regard to the health status is proved by the medical report. The medical report on the eligibility is issued by the medical doctor in charge based on the results of medical check-up or alternatively also based on other specialized examinations. In the cases when the authorized person is an employee, the medical doctor in charge is the one of the health care centre that provides preventive health care for the employer; in other cases the medical doctor in charge is the general practitioner at whom the said person is registered. The medical report on the eligibility with regard to health status of the authorized person is valid for 2 years from the date of issue, if the health status is not changed. It is not possible to acknowledge the eligibility with regard to health status in the authorized person, in whom a justified suspicion may arise that during the execution of the duties in this capacity, his/her health may be endangered, or that during the execution of the duties in the capacity of this authorized person the health or life of other persons may be endangered with regard to the health status of the said authorized person."

Current paragraphs 4 to 9 will be numbered as paragraphs 5 to 10.

18. In Section 9, paragraph 10, the numeral "30" is replaced by "10".

19. In Section 10, paragraph 1, after the word "ceilings" the word "and" is replaced with comma, after the word "floors" the words "windows and doors" are inserted, and at the end of the sentence the word "metal" is deleted and the sentence continues as follows: ", made of steel, or in a special equipment manufactured for this purpose, fitted with lock, anchored so that it cannot be detached from the wall, ceiling or floor built of solid materials (for instance bricks or concrete panels)".

20. In Section 10, paragraph 4, after the first sentence the following sentence is inserted: "However, the storage in such cases must be secured so that unauthorized persons have no access to the stored substances." In the last sentence thereof the words "Schedule 1 or 5" are replaced by "Schedule 1, 3, 4 or 5."

21. In Section 12 the existing text is marked as paragraph 1, and another paragraph 2 is added, which wording reads as follows:

"(2) Auxiliary substances, listed in Schedule 10 of this Gazette Law, may be sold only to the persons, who are authorized to handle them and who submit to the seller the filled declaration on the form issued by the Ministry of Health."

22. Section 13 including the headline and footnotes 6 and 6a reads as follows:

"Section 13

Forms of the prescriptions and of the orders marked with blue stripe

(1) The pharmaceuticals[6] containing dependency producing substances and the pharmaceuticals containing ephedrine and the pharmaceuticals containing more that 30 mg of pseudoephedrine per unit of dosage form may be dispensed in a pharmacy to a person without the handling permit solely based on a prescription or an order. In case of pharmaceuticals containing dependency producing substances, listed in Schedules 1 and 5 of this Gazette Law, the prescription or the order must be marked with blue stripe going from the left bottom corner to the right top corner. In case of pharmaceuticals containing dependency producing substances, listed in Schedules 1 and 5 of this Gazette Law, and simultaneously listed also in Schedule 8 of this Gazette Law, they may be dispensed in a pharmacy based on the prescription or the order without the marking with blue stripe.

[6] "Section 2, paragraph 1, Act No. 79/1997 Coll."

(2) The forms of the prescriptions and orders marked with blue stripe with the serial number of each form and the code of the issuing district are subject to recording.

(3) The forms of prescriptions and of the orders marked with blue stripe may be collected from the relevant local District Offices only by the persons listed in Section 5, paragraph 2, items a) and b) of this Act through their authorized proxies. These persons are obliged to keep records on further use of these substances.

(4) The District Offices arrange the production and the distribution of the prescriptions and the orders marked with blue stripe.

(5) The District Offices keeps records on supplying, returning and destruction of returned prescriptions and orders marked with blue stripe.

(6) The persons listed in Section 5, paragraph 2, items a) and b) of this Gazette Law, are obliged to return precancelled forms of prescriptions or orders marked with blue stripe to the issuing District Office.

(7) The persons who became not eligible with regard to the conditions stipulated by Section 5, paragraph 2, items a) and b) of this Gazette Law, are obliged to return through their authorized proxies the unused or precancelled forms of prescriptions of orders marked with blue stripe within 5 days to the issuing District Office. The District Office will issue a confirmation on the return of such forms.

(8) In the case of death of the person, to whom the forms of the prescriptions or the orders marked with blue stripe were given by an authorized proxy or directly by the District Office, the person, who has lived with the deceased in the common household, is obliged to return the forms within 10 days from the day of death to the authorized proxy, if the deceased person was an employee or in a similar relation. In other cases the forms are returned to the District Office.

(9) The distribution, returning and destruction, as well the keeping records on the prescriptions and the orders marked with blue stripe are governed by the specific legal regulation[6a].

(10) The pharmaceuticals containing dependency producing substances and the pharmaceuticals containing ephedrine and pseudoephedrine may not be dispensed repeatedly based on a single prescription."

23. In Section 14, the wording of paragraph 2 including footnote 6b is as follows:

"(2) The disposal of the useless dependency producing substances, preparations and precursors, which are considered to be medical drugs, as well as of the waste containing them, is governed by the specific legal regulation[6b]."

24. In the headline of Section 16, after the word "manufacturers", the words ", exporters, importers and resellers" are inserted.

25. In Section 16, after the words "to manufacture", the words "auxiliary substances" are deleted, and the words "or to export or to import auxiliary substances listed in Schedules 10 and 11 of this Gazette Law, or to sell auxiliary substances listed in Schedule 10 of this Gazette Law" are inserted; at the end of first sentence the word "manufacturing" is replaced by the word "activities".

[6a] "Public Notice No. 343/1997 Coll. whereby the methods of prescription of medical preparations, requirements for medical prescriptions and the rules of their use are stipulated."
[6b] "Section 30, Act No. 79/1997 Coll."

26. In Section 20, paragraph 1, the first sentence is replaced by the following one: "Every individual export of dependency producing substances, preparations, precursors and auxiliary substances in the cases, mentioned in paragraph 3, requires an authorization of the Ministry of Health (hereinafter only "export permit").

27. In Section 20, paragraph 2, item a), the words "in Schedules 2, 6 or 7" are replaced with the words "in Schedules 2, 6, 7 or 8 of this Gazette Law, or the preparations containing ephedrine or pseudoephedrine."

28. In Section 20, paragraph 2, item b), after the words "in Schedule 8", the words "or the preparations containing ephedrine or pseudoephedrine" are added, and at the end the words "or the preparations containing ephedrine or pseudoephedrine" are added as well.

29. In Section 20, paragraph 2, item c), the words "in Schedules 2, 5, 6 or 7" are replaced with the words "in Schedules 2, 5, 6, 7 or 8 or the preparations containing ephedrine or pseudoephedrine".

30. In Section 20, paragraph 2, item d), the words "in Schedules 1, 2, 5, 6 or 7" are replaced with the words "in Schedules 1, 2, 5, 6, 7 or 8 or the preparations containing ephedrine or pseudoephedrine".

31. In Section 20, the wording of paragraph 3 reads as follows:

"(3) The Ministry of Health stipulates by its Public Notice the cases, when the export permit is required for the export of auxiliary substances, if the export of auxiliary substances without the export permit is not allowed by an international treaty, which is binding for the Czech Republic, or if the requirement for export permit is recommended by an international governmental organization, dealing with combating illicit production of dependency producing substances and illicit trafficking in them. The information on the planned export of auxiliary substances, listed in Schedule 10, is provided to the Ministry of Health by the appropriate body of the state, where the export should be carried out, if such body requests the information through an international governmental organization, dealing with combating illicit manufacture of dependency producing substances and illicit trafficking in them."

32. In Section 21, paragraph 2, item a), the words "in Schedules 2, 6 or 7" are replaced with the words "in Schedules 2, 6, 7 or 8 or the preparations containing ephedrine or pseudoephedrine".

33. In Section 21, paragraph 2, item b), after the words "in Schedule 8" the words "or the preparations containing ephedrine or pseudoephedrine" are inserted.

34. In Section 21, paragraph 2, item c), the words "in Schedules 2, 5, 6 or 7" are replaced with the words "in Schedules 2, 5, 6, 7 or 8 or the preparations containing ephedrine or pseudoephedrine".

35. In Section 21, paragraph 2, at the end of item d) the full stop is replaced by comma and item e) is added, which wording is as follows:

"e) for the import of proprietary medical drugs, containing dependency producing substances, listed in Schedules 1, 2, 5, 6 or 7 of this Gazette Law, or the medical drugs, containing ephedrine or pseudoephedrine, if they are imported by the troops of the Army of the Czech Republic after finishing or limiting their deployment abroad within the framework of the stock, with which they were equipped."

36. In Section 26, paragraph 1, at the end of item b) the words "except for the preparations listed in Schedule 8," are added.

37. In Section 26, paragraph 1, at the end of item c) the words ", except for the preparations listed in Schedule 8," are added.

38. In Section 27, after the word "body" the words ", which has established the pharmacy" are inserted; at the end of the section the words ", except for the preparations listed in Schedule 8," are added.

39. After Section 27 a new Section 27a is inserted, which wording including footnote 10a is as follows:

"Section 27a

(1) The persons who operate the pharmacy and the distributors of pharmaceuticals[10a] are obliged at the latest by 10 January of each calendar year to report to the relevant district or municipal veterinary authority the purchases by the veterinary doctors during the past calendar year of the preparations, containing dependency producing substances, listed in Schedules 1 and 5 of this Gazette Law, except for the preparations listed in Schedule 8 of this Gazette Law.

(2) By the end of January of each calendar year, the district and municipal veterinary authorities are obliged to submit to the State Institute for the Control of Veterinary Biopreparations and Drugs the reports for the past calendar year on the consumption by the veterinary doctors of the preparations containing dependency producing substances, listed in Schedules 1 and 5 of this Gazette Law, except for the preparations listed in Schedule 8 of this Gazette Law.

(3) By the end of February the State Institute for the Control of Veterinary Biopreparations and Drugs is obliged to submit to the Ministry of Health the report for the past calendar year on the consumption by the veterinary doctors of the preparations containing dependency producing substances, listed in Schedules 1 and 5 of this Gazette Law, except for the preparations listed in Schedule 8 of this Gazette Law.

40. In the headline of Section 28, after the word "manufacturers", the words ", exporters and importers" are inserted.

41. In Section 28 the words "as manufacturers of auxiliary substances" are deleted; after the words "(Section 16)" the words "except for the resellers of auxiliary substances" are inserted; after the word "manufacture" the words "export and import" are inserted, and at the end the words "listed in Schedules 10 and 11 of this Gazette Law" are added.

42. In Section 32, after paragraph 1 a new paragraph 2 is inserted, which wording is as follows:

"(2) The export and import of auxiliary substances is subject to obligatory record keeping also by the persons to whom the provision of Section 20, paragraph 3 of this Gazette Law applies."

The existing paragraph 2 is marked as paragraph 3.

43. In Section 33, paragraph 1, after the word "substances" the words ", preparations, precursors and auxiliary substances" are inserted.

44. In Schedule 1, in the column "Narcotic drugs INN name" the words "poppy straw concentrate" are replaced with the words "poppy concentrate", and in the column "Remarks" the following text is added: "intermediate product for the production of alkaloids obtained by technological processing of poppy".

45. In Schedule 1, in the column "Remarks" for the narcotic substance "levomethorphan", the following words are added: "the isomer dextromethorphan [(+)-3-methoxy-N-methylmorphinane] is excluded from the list of narcotic substances, mentioned in this Schedule".

[10a] "Section 4, paragraph 3, Act No. 79/1997 Coll."

46. In Schedule 1, in the column "Remarks" for the narcotic substance "levorphanol", the following words are added: "the isomer dextrorphanol [(+)-3-hydroxy-N-methylmorphinane] is excluded from the list of narcotic substances, mentioned in this Schedule".

47. In Schedule 1, in the column "Remarks" for the narcotic substance "opium", the words "D6 or CH5" are replaced with "D4 or CH2".

48. The text of the note at the end of Schedule 1 reads as follows: "Including the isomers of the narcotic substances listed in this Schedule, furthermore also esters and ethers of the narcotic substances listed in this Schedule and salts of the narcotic substances listed in this Schedule, including the salts of the isomers, esters and ethers in all cases when such salts may exist."

49. The text of the note at the end of Schedule 2 reads as follows: "Including the isomers of the narcotic substances listed in this Schedule, furthermore also the salts of the narcotic substances listed in this Schedule, including the salts of the isomers of the substances listed in this Schedule in all cases when such salts may exist."

50. In Schedule 5, in the column "Another international non-proprietary name or common name", in the psychotropic substance "phencyclidine" the text is supplemented with "PCP".

51. In Schedule 5, in the column "Narcotic drugs INN name", the empty line under the word "secobarbital" is filled with the word "dronabinol", and in the column "Remarks" the following text is added: "Corresponds to such stereochemical alternatives of delta-9-THC as for instance [(-)-transdelta-9-THC]".

52. In Schedule 6, in the column "Another international non-proprietary name or common name", in the item of "kathin" the word "[(+)-norpseudoephedrine]" is added.

PART TWO
Amendment to the Act on administrative fees

Article II

The Act No. 368/1992 Coll. on administrative fees in the wording of Acts No. 10/1993 Coll., 72/1994 Coll., 85/1994 Coll., 273/1994 Coll., 36/1995 Coll., 118/1995 Coll., 140/1995 Coll., 301/1995 Coll., 151/1997 Coll., 305/1997 Coll., 149/1998 Coll., 157/1998 Coll., 167/1998 Coll., 63/1999 Coll., 166/1999 Coll., 167/1999 Coll., 223/1999 Coll., 326/1999 Coll., 352/1999 Coll., 357/1999 Coll., 360/1999 Coll., 363/1999 Coll., 46/2000 Coll. and 62/2000 Coll. is amended as follows:

In the Tariffs of Administrative Fees in article 131b, the items d) and e) are added together with the note, which all read as follows:

"d) Registration of manufacturers, importers and exporters of auxiliary substances -
CZK 1,000
e) Registration of resellers of auxiliary substances –
CZK 1,000

Note:

The fee pursuant to item d) of this article is collected for the registration of manufacturers, importers and exporters of auxiliary substances, which are listed in Schedules 10 and 11 of the Act No. 167/1998 on dependency producing substances and on amendment of some other acts, in the wording of Act No. 117/2000 Coll. The fee

pursuant to item e) of this article is collected for the registration of resellers of auxiliary substances, which are listed in Schedule 10 of the same Act."

PART THREE
Effective date

Article III

This Gazette Law shall become effective as of 30 June 2000 with the exception of Art. I, item 22, as far as the provision of Section 13, paragraph 2 is concerned, which shall become effective as of 30 June 2001.

Signed by

Klaus

Havel

Zeman

E/NL.2001/63

Public Notice N°143 of the Ministry of Health of 25 May 2000

whereby the Public Notice of the Ministry of Health No. 304/1998 Coll. is amended[1], wherein it is stipulated in which cases the export permit for the export of auxiliary substances is not required, and what are the details of keeping records on addictive substances, preparations and precursors, and of the documentation on addictive substances[2].

Pursuant to § 20, Art. 3, § 32, Art. 3 and § 33, Art. 3 of the Act No. 167/1998 Coll. on addictive substances and on the amendment to some other acts, as amended by the Act No. 117/2000 Coll., the Ministry of Health stipulates herewith:

Article I

Public Notice No. 304/1998 Coll., wherein it is stipulated in which cases the export permit for the export of auxiliary substances is not required, and what are the details of keeping records on addictive substances, preparations and precursors, and of the documentation on addictive substances, is amended as follows:

1. In §1, after the words "in Annex 10" the words "and in Annex 11" are inserted.

2. In § 2, in Article 4 at the end of second sentence the following words are added: "also in the case when no changes have been entered during the calendar month". At the end of the Article the following words are added: "including the responsible person, if he/she has been appointed. In the case no responsible person has been appointed, the record on the control is signed by the owner of the business himself/herself, if he/she fulfils the requirements for the responsible person in the sense of § 8, Art. 6 of the Act.".

3. In § 4, after Article 1 the new Article 2 is added, which reads as follows:

   "(2) Computerized keeping of records must be run so as to allow separate daily monitoring of changes and quantities of the stock in individual ready-made proprietary pharmaceutical products, listed in Annexes 2, 6 and 7 of the Act, and in the pharmaceutical products, containing ephedrine or pseudoephedrine, and to allow their retrospective detection for the period of 5 years.

   Current Articles 2 to 4 are numbered as Articles 3 to 5.

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[1] Note by the Secretariat: E/NL.2001/62

[2] Note by the Secretariat: this notice contained 6 annexes entitled: **Schedule 1** “Cases when the export authorization for the export of essential chemicals is required”, **Schedule 2** “A specimen of a page of the record book for pharmacies”, **Schedule 3** “The lay-out of a page of the record book in other health institutions, welfare institutions and when providing veterinary care**” Schedule 4** “A specimen of a page of the record book of the production of preparations that contain dependency producing substances (HD)”, **Schedule 5** “A specimen of a page of the record book of the storing”, **Schedule 6** “Customer declaration showing the specific use(s) of the category 2 substances” which are not reproduced here. They can be consulted with the Secretariat.

4. In § 4, Art. 5, the second sentence reads as follows: "After the stocktaking the protocol will be made, which will contain the items required pursuant to § 2, Art. 4, including the statement on the initial quantity at the beginning of the monitored period, total quantities received and dispensed, and the quantity on stock of all monitored items as of the day of stocktaking.
5. After § 6 the new § 6a is inserted, which wording including the headline is as follows:

"§ 6a
Keeping of records on addictive substances listed in Annexes No. 3 and 4 of the Act and on the preparations containing such substances

(1) Legal persons and natural persons (self-employed) keep the records on handling both the addictive substances, listed Annexes 3 and 4, and the preparations containing such substances.

(2) The form of the book for keeping the records pursuant to Article (1) is stipulated by Annex 6 of this Public Notice.".

6. In § 9, Art. 1, after item g) the new item h) is inserted, which reads as follows:

"h) all official decisions concerning the registration of manufacturers, exporters, importers and resellers of auxiliary substances, and all decisions concerning exports and imports,".

Current items h) to j) are marked as items i) to k).

7. In § 9, Art. 1, item j), in the part of the sentence after the comma the word "or" is replaced by comma. After the word "precursors" the following words are added: "or auxiliary substances listed in Annex 10 of the Act.".

8. In § 9, Art. 1, at the end of item k) the full stop is replaced by comma and the new item l) is added, which reads as follows:

"l) declaration of the legal persons and natural persons (self-employed), who handle the auxiliary substances, listed in Annex 10 of this Act. The requirements for this declaration are mentioned in Annex 7 to this Public Notice.".

9. In § 10, the second sentence reads as follows: "The records pursuant to § 9, Art. 1, item c), d), e) or k) must be always signed by the responsible person (§ 9 of the Act). In the case the responsible person has not been appointed, the record is signed by the owner of the business himself/herself, if he/she fulfils the requirements for the responsible person in the sense of § 8, Art. 6 of the Act.".

10. In § 11 after the word "preparations", the conjunction "and" is replaced by comma, and after the word "precursors" the following words are inserted: "and auxiliary substances listed in Annexes 10 and 11 of the Act.".

11. After Annex 5 the new Annexes 6 and 7 are added, which wording is as follows:

Article II
Effective date
This Public Notice shall become effective as of 1 July 2000.

Signed by
Minister:
Prof. MUDr. Fišer, CSc.