UNITED NATIONS

E/NL.2003/35-40
16 July 2003
English only (*)

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

NETHERLANDS

Communicated by the Government of Netherlands

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 [...].

CONTENTS **PAGE**

(*)Note by the Secretariat: These documents are a direct reproduction of the texts communicated to the Secretariat.

V.03-86331 (E)

E/NL.2003/35

Opium Act, as after [enactment] of the Act of 13 July, 2002, to amend the Opium Act (Staatsblad *[Bulletin of Acts and Decrees]* 2002, 520), and the Decree to actualise the Lists I and II of the Opium Act (Staatsblad 2002, 623), which Decree will be enacted simultaneously with the aforementioned Act

Law of 12 May 1928, containing regulations concerning opium and other narcotic substances (Opium Act)

Article 1

1. In this Act and the provisions based on it, the following terms shall have the following meanings:
   a. *'Our Minister':* Our Minister of Public Health and Environmental Protection;
   b. *'substance':* a substance with a human, animal, plant or chemical origin, including animals, plants, parts of animals or plants, as well as micro-organisms;
   c. *'preparation':* a solid or liquid mixture of substances;
   d. *'drug':* substance or preparation;
   e. *'Single Convention':* the Single Convention on Narcotic Drugs concluded in New York on 30 March 1961 (*Trb.* [*Bulletin of Treaties*] 1963, 81), as amended by the Protocol to Amend that Convention concluded in Geneva on 25 March 1972 (*Trb*. 1987, 90);
   f. *'Convention on Psychotropic Substances':* the Convention on Psychotropic Substances concluded in Vienna on 21 February 1971 (*Trb.* 1989, 129);
   g. '*Joint Action*': the Joint Action No. 97/396/JHA of 16 June 1997 adopted by the Council of the European Union based on Article K.3 of the Treaty on European Union, on the information exchange, risk assessment and control of new synthetic drugs (*OJ L* 167).
2. For purposes of the application of this Act and the provisions based on it, the salts of the substances shall be considered equivalent to those substances.
3. For purposes of the application of this Act, 'manufacture' shall include refining and converting.
4. 'Bringing drugs into the territory of the Netherlands' as referred to in Articles 2 and 3 shall include: bringing objects or goods into the territory of the Netherlands in which those drugs have been packaged or stored and every act of further transport, storage, supply, receipt or transfer with regard to those drugs which have been brought into the territory of the Netherlands or with regard to the objects or goods in which those drugs have been packaged or stored.
5. 'Bringing drugs outside the territory of the Netherlands' as referred to in Articles 2 and 3 shall include: bringing objects or goods outside the territory of the Netherlands in which those drugs have been packaged or stored and the transport to a foreign destination, acceptance for transport or presentation for transport or declaration for export or re-export, including giving notice of the re-export, within the meaning of Regulation (EEC) No. 2913/92 of the Council of the European Communities of 12 October 1992 establishing the Community Customs Code (*OJ L* 302) of those drugs or of those objects or goods, or possession of those drugs or those objects or goods in, on or at a vessel, vehicle or aircraft travelling to a foreign destination.

Article 2

It shall be illegal to:
A. bring into or outside the territory of the Netherlands;
B. prepare, treat, process, sell, supply, provide or transport;
C. possess; or
D. manufacture

a drug as referred to in List I accompanying this Act or designated pursuant to Article 3a, fifth paragraph.

Article 3

It shall be illegal to:
A. bring into or outside the territory of the Netherlands;
B. grow, prepare, treat, process, sell, supply, provide or transport;
C possess; or

D. manufacture
a drug as referred to in List II accompanying this Act or designated pursuant to Article 3a, fifth paragraph.

Article 3a

1. Drugs shall be added to the List I or List II accompanying this Act by an order in council if they are brought within the scope of the Single Convention or the Convention on Psychotropic Substances or, pursuant to an obligation arising under the Joint Action, must be brought within the scope of this Act. Drugs may be deleted from List I or II by an order in council if they are removed from the scope of the Conventions referred to in the first sentence or if the obligation referred to in that sentence is extinguished on account of the Joint Action.
2. Drugs may be added to List I or List II by an order in council if it is shown that they have an affect on the consciousness of a human being and that, if used by a human being, they are damaging to his health and detrimental to society.
3. Drugs which have been added by an order in council pursuant to the second paragraph may be deleted from List I or List II if it is shown that they do not or no longer have the characteristics referred to in the second paragraph.
4. An order in council as referred to in the first, second and third paragraph shall not be adopted until four weeks have passed since the draft of the order was presented to both Houses of the States General and, during that time period, a wish was not expressed by or on behalf of either of the Houses for the subject regulated in the draft of the order to be regulated by statute.
5. If, in our Minister's judgment, acts as referred to in Article 2 or 3 in respect of a drug must immediately be prohibited and the formulation of an order in council as referred to in the first or second paragraph cannot be awaited, the drug may be designated by ministerial regulation. Our Minister shall ensure that, at the same time that this ministerial regulation is adopted, the draft of an order in council with the same content shall be presented to the Council of Ministers for evaluation. Unless withdrawn earlier, the ministerial regulation shall remain in effect until the order in council designating the drug concerned takes effect, but no later than up to a year after the regulation becomes effective.

Article 3b

1. Any publication which is clearly intended to promote the sale, supply or provision of a drug as referred to in Article 2 or Article 3 shall be prohibited.
2. The prohibition contained in the first paragraph shall not apply in respect of publication related to medical or scientific information.

Article 3c

1. An order in council may designate drugs and applications for which a prohibition described in Article 2 or 3 does not apply in whole or in part.
2. With regard to drugs as referred to in List I or II, an order in council may lay down rules to ensure compliance with the provisions of the Single Convention or the Convention on Psychotropic Substances or to prevent abuse of those drugs.

Article 4

1. It shall be illegal to issue a prescription for a drug as referred to in List I or II, unless, in the interest of public health, the drug has been designated for this purpose by an order in council. The order may lay down rules concerning the prescription and the purpose for which the drug shall be prescribed.
   An order in council adopted pursuant to the first sentence shall not take effect until eight weeks after the date of issue of the *Staatsblad* [Bulletin of Acts and Decrees] in which it has been published. The publication shall be reported immediately to both Houses of the States General. In the interest of public health and in deviation from the first sentence, a drug may be designated by ministerial regulation for which a prescription may be issued, as long as the drug has also been designated pursuant to Article 3a, fifth paragraph.
2. The ordering of a drug as referred to in List I or II by:
   a. professionals as referred to in Article 5, first paragraph,
   b. institutions and persons as referred to in Article 5, second paragraph and third paragraph, and
   c. holders of an exemption as referred to in Article 6,
   shall occur with due observance of the rules adopted by ministerial regulation.

3. With respect to obtaining any drug referred to in List I and II, it shall be illegal:
   a. to present a fake or forged prescription;
   b. to present a prescription in which a different name or a different address is stated than the name or the address of the person on whose behalf the prescription was issued.

Article 5

1. An order in council may lay down rules regarding the supply of drugs designated pursuant to Article 4. Subject to this order in council, the prohibition on preparing, treating, processing, selling, supplying, providing, transporting or possessing a drug referred to in List I or II shall not apply to:
   a. pharmacists or doctors operating pharmacies if, for medical purposes, they prepare, treat, process, sell, supply, provide, transport or possess drugs designated pursuant to Article 4, first paragraph, and these activities occur within the normal practice of their professions;
   b. veterinary surgeons if, for veterinary medicine purposes, they sell, supply, provide, transport or possess the drugs designated pursuant to Article 4.
2. The prohibitions on providing, transporting or possessing drugs as referred to in List I or II shall also not apply to institutions designated by an order in council and to those who need the drugs in question in the quantity present to practice medicine, dentistry or veterinary medicine or for their own medical use or must have them in stock pursuant to statutory provisions and have obtained them in a legal manner.
3. In addition, if an emergency situation as referred to in Article 1, first paragraph, of the National Emergencies Act is proclaimed, other institutions or persons besides those referred to in the first and second paragraph may be designated by royal decree, at Our Minister's recommendation, for which/whom the prohibitions on providing, transporting or possessing drugs as referred to in List I or II shall not apply. This designation may be limited to certain areas and certain drugs. Further conditions may also be attached to the designation. The designation shall expire by law if the emergency situation is terminated and may also be revoked by royal decree, at Our Minister's recommendation.
4. Moreover, the prohibition on transport and possession shall not apply to those who transport or possess the drugs at the instruction of a person who is authorised to engage in such transport.

Article 6

1. With due observance of Article 8i, first paragraph, Our Minister may grant an exemption from a prohibition as referred to in Article 2 or 3. He may also extend, modify, supplement or revoke an exemption.
2. An exemption or an extension thereof may be granted for at most five years, on the understanding that an exemption from a prohibition as referred to in Article 2, under A, or Article 3, under A, shall be granted on a case-by-case basis and for at most six months.
3. Our Minister shall inform the applicant for an exemption or for an extension thereof of his decision within three months after receiving the application.

Article 7

1. A fee may be levied for processing an application for an exemption or a modification of, addition to or extension thereof. No fee shall be owed for processing an application for an exemption as referred to in Article 8i, second paragraph.
2. A fee may be levied annually for an exemption. The provisions of the first paragraph, second sentence, shall apply by analogy to the annual fee.
3. The amount of the fees referred to in the first and second paragraph shall be set by ministerial regulation and may be set in a different manner for each category of exemptions. If an exemption applies for a period of less than one year, the fee referred to in the second paragraph shall be set proportionately at a lower amount.

Article 8

1. An exemption may only be granted or extended if the applicant has demonstrated to Our Minister's satisfaction:
   a. that this shall serve the interest of public health or that of the health of animals;

b. that the applicant needs this to perform scientific or analytical chemical research or for instructional purposes, insofar as the interest of public health does not dictate otherwise, or
c. that the applicant needs this to perform an act as referred to in Article 2 or 3 pursuant to an agreement with:
   1. another person to whom an exemption has been granted pursuant to Article 6, first paragraph;
   2. a pharmacist or a doctor operating a pharmacy;
   3. a veterinary surgeon;
   4. an institution or person designated pursuant to Article 5, second or third paragraph;
   5. a holder of a permit or exemption granted in another country to import the drugs in question into that country, insofar as the interest of public health does not dictate otherwise.

2. An exemption may also be granted or extended if the applicant needs this to grow cannabis pursuant to an agreement with Our Minister.

Article 8a

1. Conditions may be attached to an exemption to ensure compliance with the provisions of the Single Convention and the Convention on Psychotropic Substances and the rules laid down in or pursuant to this Act, or to prevent abuse of a drug as referred to in List I or II.
2. The exemption shall at least state:
   a. the prohibitions as referred to in Article 2 or 3 for which it is being granted;
   b. the purposes for which it is being granted;
   c. on which property and in which locations the acts in question may take place;
   d. the manner of storage;
   e. the manner of safeguarding;
   f. the manner in which the stock records have been set up.

Article 8b

An exemption or an extension thereof shall be denied if, pursuant to a judicial decision which has become final and conclusive, the applicant has been placed under guardianship or an administrator has been appointed over his property.

Article 8c[1]

1. An exemption or an extension thereof may be denied in the event of and under the conditions referred to in Article 3 of the Public Administration Probity in Decision-making Act.
2. With an eye to the application of the first paragraph, the *Bureau bevordering integriteitsbeoordelingen door het openbaar bestuur* [Office for Public Administration Probity in Decision-making] referred to in Article 8 of the Act referred to in the first paragraph may be asked for an advisory opinion as referred to in Article 9 of that Act.

Article 8d

An exemption shall be revoked:

a. at the request of the holder of the exemption;
b. if the interest of public health requires this;
c. if, in Our Minister's judgment, the purposes for which the exemption was granted can no longer be realised;
d. if a fee owed pursuant to Article 7, second paragraph, has not been paid within 30 days after being levied, nor has there been compliance with the written demand of Our Minister, made after that time period has lapsed, to pay within eight days.

Article 8e[2]

1. An exemption may be revoked:
   a. if the holder of the exemption acts contrary to a rule laid down in or pursuant to this Act;

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[1] Article 8c will be enacted when the Public Administration Probity in Decision-making Act (*Bulletin of Acts and Decrees]* 2002, 347) will be enacted, i.e on 1 June 2003).

[2] Article 8e, first paragraph, under b, and second paragraph, will be enacted when the Public Administration Probity in Decision-making Act (*Bulletin of Acts and Decrees]* 2002, 347) will be enacted, i.e on 1 June 2003).

b. in the event of and under the conditions referred to in Article 3 of the Public Administration Probity in Decision-making Act.

2. With an eye to the application of the first paragraph, under b, the Office for Public Administration Probity in Decision-making referred to in Article 8 of the Act referred to in the first paragraph, under b, may be asked for an advisory opinion as referred to in Article 9 of that Act.

Article 8f

1. A person whose exemption is revoked shall dispose of the drugs to which the exemption pertains during the time period between the notification of the revocation and the last day on which the exemption is valid. He shall dispose of these drugs either by destroying them or transferring them to persons, including legal persons, which are authorised to perform acts as referred to in Article 2 or 3.
2. In deviation from the first paragraph, the holder of an exemption for growing hemp shall dispose of the drugs to which the exemption pertains either by destroying those drugs or transferring them to Our Minister.

Article 8g

An exemption shall cease to have effect:

a. if the holder dies;
b. if, pursuant to a judicial decision which has become final and conclusive, the applicant has been placed under guardianship or an administrator has been appointed over his property;
c. if the legal person to which the exemption was granted is dissolved, merges and is not the acquiring legal person, or is split up.

Article 8h

Our Minister shall ensure that:

a. enough hemp is grown in the Netherlands for scientific research into the medical application of hemp, hashish and hempseed oil or for the production of medicines;
b. the hemp grown as referred to under a is used for a purpose referred to under a.

Article 8i

1. Our Minister shall not grant any more exemptions from the prohibition on growing hemp than are necessary for the purposes referred to in Article 8h and for refining hemp.
2. An exemption from the prohibition on growing hemp or processing, treating or transporting hemp, hashish and hempseed oil for the purposes referred to in Article 8h shall only be granted to the person with whom Our Minister enters into an agreement in this regard to perform such acts.
3. An agreement as referred to in the second paragraph shall end by law as from the date on which the exemption granted to the other party is revoked or expires.
4. An agreement as referred to in the second paragraph shall in any case state that the other party with whom Our Minister is entering into the agreement shall exclusively sell and deliver to him the hemp grown within four months after it is harvested and shall destroy the surplus hemp.
5. To the exclusion of others, Our Minister shall be authorised:
   a. to bring hemp, hashish and hempseed oil into and outside the territory of the Netherlands;
   b. to sell and supply hemp, hashish and hempseed oil;
   c. to possess hemp, hashish and hempseed oil, with the exception of the stocks managed by those who have an exemption to grow, treat or process these drugs.
6. The fifth paragraph shall not be applicable insofar as applications of hemp, hashish or hempseed oil have been designated pursuant to Article 3c, first paragraph.

Article 8j

The civil servants of the *Staatstoezicht op de Volksgezondheid* [Public Health Inspectorate], and the civil servants of the *Belastingdienst* [Tax Department], insofar as they are competent with regard to customs, shall be responsible for monitoring compliance with the provisions of or pursuant to this Act.

Article 8k

In addition to the persons designated in or pursuant to Article 141 of the Dutch Code of Criminal Procedure, the civil servants referred to in Article 8j shall be responsible for investigating the offences made punishable in this Act.

Article 9

1. Insofar as reasonably necessary to perform their duties, the investigating officials shall have access to:
   a. the means of transport, including residential portions, which they know or which they reasonably may suspect are used to import or transport drugs as referred to in List I or II, or in which, on which or at which these drugs are stored or present;
   b. the locations where a violation of this Act is being committed or where it may reasonably be suspected that such a violation is being committed.
2. In the event of grave presumptions against a person suspected of an offence made punishable as a crime by this Act, they shall be authorised to search this person's clothing.
3. They shall be authorised at all times to seize objects which are capable of being seized. To this end, they may demand their delivery.
4. The Public Prosecutor or Assistant Public Prosecutor before whom the suspect is brought or who themselves have arrested the suspect shall be authorised to order a person who has just entered the territory of the Netherlands or who is about to leave this territory, and who has been arrested in connection with an offence made punishable as a crime by this Act, to cooperate in a urinalysis designed to demonstrate the presence in the body of drugs as referred to in article 2 or 3, first paragraph. [3]

Article 10

1. A person acting contrary to:
   a. a prohibition given in Article 2, the prohibition given in Article 3b, first paragraph, or a prohibition given in Article 4, third paragraph;
   b. a rule given pursuant to Article 3c, second paragraph, or Article 4, first or second paragraph;
   c. a condition attached to an exemption pursuant to Article 8a, first paragraph;
   shall be punished with imprisonment of at most six months or a fine of the fourth category.
2. A person wilfully acting contrary to the prohibition given in Article 2, under C, in Article 3b, first paragraph, or in Article 4, third paragraph, shall be punished with imprisonment of at most four years or a fine of the fifth category.
3. A person wilfully acting contrary to the prohibition given in Article 2, under B or D, shall be punished with imprisonment of at most eight years or a fine of the fifth category.
4. A person wilfully acting contrary to a prohibition given in Article 2, under A, shall be punished with imprisonment of at most 12 years or a fine of the fifth category.
5. If the offence referred to in the second or fourth paragraph pertains to a small quantity intended for personal use, imprisonment of at most one year or a fine of the third category shall be imposed.

Article 10a

1. If, in order to prepare for or encourage an offence referred to in the third or fourth paragraph of Article 10, a person:
   1. attempts to induce another person to commit that offence, to have that offence committed, to participate in committing that offence or to incite someone to commit that offence, to aid and abet in this regard, or to provide the opportunity, means or information for this,
   2. attempts to obtain for himself or another person the opportunity, means or information to commit that offence,
   3. has objects, means of transport, substances, money or other means of payment on hand which he knows or has serious reason to suspect are intended for the commission of that offence,
   shall be punished with imprisonment of at most six years or a fine of the fifth category.
2. A person committing the offences described in the first paragraph shall not be punished with regard to bringing into or outside the territory of the Netherlands a small quantity intended for personal use.

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[3] A bill amending this article is proposed to parliament on 13 January 2003. If accepted, this article will read: "The Public Prosecutor or Assistant Public Prosecutor before whom the suspect is brought or who themselves have arrested the suspect shall be authorised to order a person who has just entered the territory of the Netherlands or who is about to leave this territory, and who has been arrested in connection with an offence made punishable as a crime by this Act, to cooperate in a urinalysis designed to demonstrate the presence in the body of drugs as referred to in List I and II."

Article 11

1. A person acting contrary to a prohibition given in Article 3 shall be punished with imprisonment of at most one month or a fine of the second category.
2. A person wilfully acting contrary to a prohibition given in Article 3, under B, C or D, shall be punished with imprisonment of at most two years or a fine of the fourth category.
3. A person wilfully acting contrary to a prohibition given in Article 3, under B, in connection with practising a profession or operating a business shall be punished with imprisonment of at most four years or a fine of the fifth category.
4. A person wilfully acting contrary to a prohibition given in Article 3, under A, shall be punished with imprisonment of at most four years or a fine of the fifth category.
5. The second paragraph shall not apply if the offence pertains to a quantity of hemp or hashish of at most 30 grams.
6. The second and fourth paragraph shall not apply if the offence pertains to a small quantity, intended for personal use, of the drugs stated in list referred to in Article 3, first paragraph.[4]

Article 12

If the value of the objects with which or with regard to which the offences made punishable in Articles 10, first, second, third and fourth paragraph, 10a, first paragraph, and 11, second and third paragraph, were committed, or which were obtained in full or in part through those offences, is higher than one-fourth of the maximum of the fine imposed for those offences, a fine of the next highest category may be imposed, even if the offence was committed by a natural person.

Article 13

1. The offences made punishable in Article 10, first paragraph, and Article 11, first paragraph, are minor offences.
2. The offences made punishable in Article 10, second, third, fourth and fifth paragraph, in Article 10a, first paragraph, and in Article 11, second, third and fourth paragraph, are crimes.
3. The Dutch criminal laws shall apply to everyone who, outside the Netherlands, is guilty of:
   a. one of the offences made punishable in Article 10a, first paragraph, insofar as they were committed to prepare for or to encourage the offence made punishable in Article 10, fourth paragraph, or
   b. attempting to or participating in the offence made punishable in Article 10, fourth paragraph.

Article 13a

Subject to the provisions in Articles 33 to 35 inclusive and 36b to 36d inclusive of the Dutch Criminal Code, the drugs referred to in List I or II shall be forfeited or confiscated.

Article 13b

1. The Mayor shall be authorised to apply administrative coercion if, in buildings accessible to the public and the property on which they are located, a drug as referred to in List I or II is sold, delivered or provided, or is present for this purpose.
2. The first paragraph shall not apply if the buildings in question are used for preparing medicines or practising medicine, dentistry or veterinary medicine by pharmacists, doctors, dentists and veterinary surgeons respectively.
3. If, based on the first paragraph, the Mayor has decided to close the building or property in question, he shall have this order registered as soon as possible in the public registers referred to in Article 16 of Book 3 of the Dutch Civil Code. Article 24 of that Code shall not be applicable.

Article 14

This Act may be cited as the 'Opium Act'.

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[4] A bill amending this article is proposed to parliament on 13 January 2003. If accepted, this article will read: The second and fourth paragraph shall not apply if the offence pertains to a small quantity, intended for personal use, of the drugs stated in list II, with the exception of hemp and hashish.

Article 15
This Act shall take effect as from a date to be determined by Us.
On that date, the Act of 4 October 1919, *Bulletin of Acts and Decrees* No. 592, Adopting Provisions concerning Opium and Other Illicit Drugs, as this Act was amended by the Act of 29 June 1925, *Bulletin of Acts and Decrees* No. 308, shall cease to have effect.

We hereby order and command that this be published in the *Bulletin of Acts and Decrees* and that all Ministerial Departments, Authorities, Boards and Civil Servants that it concerns remain involved in its precise implementation.

Rendered at *Paleize het Loo* [Royal Palace Het Loo], 12 May 1928.

WILHELMINA.

List I

(The lists I and II are translated only as far as required for proper understanding)

International non-proprietary name (inn)[5]	Other names	Further description
acetorfine	-	
-	acetyl-*alfa*-methylfentanyl	*N*-[1-(*alfa*-methylfenethyl)-4-piperidyl]-acetanilide
-	acetyldihydrocodeïne	4,5-epoxy-3-methoxy-*N*-methylmorfinan-6-yl-acetaat
acetylmethadol	-	
alfacetylmethadol	-	
alfameprodine	-	
alfamethadol	-	
-	*alfa*-methylfentanyl	*N*-[1(*alfa*-methylfenethyl)-4-piperidyl]-propionanilide
-	*alfa*-methylthiofentanyl	*N*-[1-[1-methyl-2-(2-thienyl)ethyl]-4-piperidyl]propionanilide
alfaprodine	-	
alfentanil	-	
allylprodine	-	
amfetamine	-	
anileridine	-	
benzethidine	-	
-	benzylmorfine	3-benzoyloxy-4,5-epoxy-*N*-methyl-7-morfineen-6-ol
betacetylmethadol	-	
-	*beta*-hydroxy-3-methylfentanyl	*N*-[1-(*beta*-hydroxyfenethyl)-3-methyl-4-piperidyl]propionanilide
-	*beta*-hydroxyfentanyl	*N*-[1-(*beta*-hydroxyfenethyl)-4-piperidyl]-propionanilide
betameprodine	-	
betamethadol	-	
betaprodine	-	
bezitramide	-	
-	poppy straw	all parts of the *Papaver somniferum L.* plant after harvesting, except for the seed
brolamfetamine	-	
cathinon	-	
-	2C-B	4-bromo-2,5-dimethoxyfenetylamine
clonitazeen	-	
-	coca leaves	leaves of plants of the genus Erythroxylon
-	cocaïne	(-)-3-*beta*-benzoyloxytropaan-2-*beta*- carboxylic acid methylester
-	codeïne	4,5-epoxy-3-methoxy-*N*-methyl-7-morfineen-6-ol
codoxim	-	
-	concentrate of poppy straw	the material obtained by subjecting poppy straw to a treatment to concentrate the alkaloids in it
desomorfine	-	
dexamfetamine	-	
dextromoramide	-	
dextropropoxyfeen	-	
diampromide	-	

[5] The generic name adopted by the World Health Organization.

International non-proprietary name (inn)[5]	Other names	Further description
diëthylthiambuteen	-	
-	*N,N*-diëthyltryptamine, DET	3-[2-(diethylamino)ethyl]indol
difenoxine	-	
difenoxylaat	-	
dihydrocodeïne	-	
-	dihydroethorfine	7,8-dihydro-7-*alfa*-[1-(*R*)-hydroxy-1-methylbutyl]-6,14-*endo*-ethano-tetrahydro-oripavine
-	dihydromorfine	4,5-epoxy-*N*-methylmorfinan-3,6-diol
dimefeptanol	-	
dimenoxadol	-	
-	2,5-dimethoxy-amfetamine, DMA	(±)-2,5-dimethoxy-*alfa*-methylfenethylamine
-	2,5-dimethoxy-4-ethyl-amfetamine, DOET	(±)-4-ethyl-2,5-dimethoxy-*alfa*-methylfenethylamine
-	2,5-dimethoxy-4-methamfetamine, STP, DOM	2,5-dimethoxy-*alfa*,4-dimethylfenethylamine
dimethylthiambuteen	-	
-	*N,N*-dimethyltryptamine, DMT	3-[2-(dimethylamino)ethyl]indol
dioxafetylbutiraat	-	
dipipanon	-	
-	DMHP	3-(1,2-dimethylheptyl)-7,8,9,10-tetrahydro-6,6,9-trimethyl-6*H*- dibenzo[*b,d*]pyran-1-ol
drotebanol	-	
-	ecgonine	3-hydroxy-2-tropaancarbonzuur
-	*N*-ethyl-3,4-methyleendioxy-amfetamine, *N*-ethyl-MDA	(±)-*N*-ethyl-*alfa*-methyl-3,4-(methyleen-dioxy)fenethylamine
ethylmethylthiambuteen	-	
-	ethylmorfine	4,5-epoxy-3-ethoxy-*N*-methyl-7-morfineen-6-ol
eticyclidine	-	
etonitazeen	-	
etorfine	-	
etoxeridine	-	
etryptamine	-	
fenadoxon	-	
fenampromide	-	
fenazocine	-	
fencyclidine	-	
fenetylline	-	
fenmetrazine	-	
fenomorfan	-	
fenoperidine	-	
fentanyl	-	
folcodine	-	
-	furethidine	1-(2-tetrahydrofurfuryloxyethyl)-4-fenyl-piperidine-4-carboxylic acid ethylester
-	hempseed oil	concentrate of plants of the genus Cannabis (hemp) obtained by extraction of hemp or hashish, whether mixed with oil or not

International non-proprietary name (inn)[5]	Other names	Further description
-	heroïne, diamorfine	4,5-epoxy-17-methylmorfinan-3,6-diyl-diacetaat
hydrocodon	-	
hydromorfinol	-	
hydromorfon	-	
-	*N*-hydroxymethyleen-dioxy-amfetamine, *N*-hydroxyMDA	(±)-*N*-[*alfa*-methyl-3,4-(methyleendioxy)-fenethyl]hydroxylamine
hydroxypethidine	-	
isomethadon	-	
ketobemidon	-	
levamfetamine	-	
levofenacylmorfan	-	
-	levomethamfetamine	(-)-*N*,*alfa*-dimethylfenethylamine
levomethorfan	-	
levomoramide	-	
levorfanol	-	
lysergide		
mecloqualon	-	
-	mescaline	3,4,5-trimethoxyfenethylamine
metamfetamine	-	
metamfetamine racemaat	-	
metazocine	-	
methadon	-	
-	methadon intermediate product	4-cyano-2-dimethylamino-4,4-difenylbutaan
methaqualon	-	
-	methcathinon	(2-methylamino)-1-fenylpropaan-1-on
-	2-methoxy-4,5-methyleendioxy-amfetamine, MMDA	2-methoxy-*alfa*-methyl-4,5-(methyleendioxy)-fenethylamine
-	4-methylaminorex	(±)-*cis*-2-amino-4-methyl-5-fenyl-2-oxazoline
methyldesorfine	-	
methyldihydromorfine	-	
-	3,4-methyleendioxy-methamfetamine, MDMA	(±)-*N*,*alfa*-dimethyl-3,4-(methyleendioxy)-fenethylamine
methylfenidaat	-	
-	3-methylfentanyl	*N*-(3-methyl-1-fenethyl-4-piperidyl)propion-anilide
-	MPPP	1-methyl-4-fenyl-4-piperidinol propionaat (ester)
-	4-methylthioamfetamine, 4-MTA	4-methylthio-*alfa*-methylfenethylamine
-	3-methylthiofentanyl	*N*-[3-methyl-1-[2-(2-thienyl)ethyl]-4-piperidyl]propionanilide
metopon	-	
-	moramide intermediate product	2-methyl-3-morfolino-1,1-difenylpropaan-carboxylic acid
morferidine	-	
-	morfine	4,5-epoxy-*N*-methyl-7-morfineen-3,6-diol
-	morfine-methobromide	4,5-epoxy-*N*-methyl-7-morfineen-3,6-diol methylbromide
-	morfine-*N*-oxide	4,5-epoxy-3,6-dihydroxy-*N*-methyl-7-morfine
myrofine	-	
nicocodine	-	

International non-proprietary name (inn)[5]	Other names	Further description
nicodicodine	-	
nicomorfine	-	
noracymethadol	-	
norcodeïne	-	
norlevorfanol	-	
normethadon	-	
normorfine	-	
norpipanon	-	
-	opium	the curdled milk obtained from the Papaver somniferum L. plant
oxycodon	-	
oxymorfon	-	
-	*para*-fluorfentanyl	4'-fluoro-*N*-(1-fenethyl-4-piperidyl)propion-anilide
-	parahexyl	3-hexyl-7,8,9,10-tetrahydro-6,6,9-trimethyl-6*H*-dibenzo[*b,d*]pyran-1-ol
-	*para*-methoxy-amfetamine, PMA	*p*-methoxy-*alfa*-methylfenethylamine
-	*para*-methoxymeth-amfetamine, PMMA	*N*-methyl-1-(4-methoxyfenyl)-2-aminopropaan
-	PEPAP	1-fenethyl-4-fenyl-4-piperidinolacetaat (ester)
pethidine	-	
-	pethidine intermediate product A	4-cyano-1-methyl-4-phenylpiperidine
-	pethidine intermediate product B	4-phenylpiperidine-4-carboxylic acid ethylester
-	pethidine intermediate product C	1-methyl-phenylpiperidine-4-carboxylic acid
piminodine	-	
piritramide	-	
proheptazine	-	
properidine	-	
propiram	-	
-	psilocine	3-[2-(dimethylamino)ethyl]indol-4-ol
psilocybine	-	
racemethorfan	-	
racemoramide	-	
racemorfan	-	
remifentanil	-	
rolicyclidine	-	
secobarbitone	-	
sufentanil	-	
tenamfetamine	-	
tenocyclidine	-	
-	tetrahydrocannabinol	(6*aR*,10*aR*)-6*a*,7,8,10*a*-tetrahydro-6,6,9-trimethyl-3-pentyl-6*H*-dibenzo[*b,d*]pyran-1-ol
thebacon	-	
-	thebaïne	4,5-epoxy-3,6-dimethoxy-*N*-methyl-6,8-morfine
-	thiofentanyl	*N*-[1-[2-(2-thienyl)ethyl]-4-piperidyl]propion-anilide
tilidine	-	
trimeperidine	-	
-	3,4,5-trimethoxy-amfetamine, TMA	(±)-3,4,5-trimethoxy-*alfa*-methylfenethylamine
zipeprol	-	

The esters and derivatives of ecgonine, which may be converted into ecgonine and cocaine;

the mono- and di-alkylamide, pyrrolidine and morpholine derivatives of lysergic acid, and the drugs obtained by introducing methyl, acetyl or halogen groups;

pentavalent nitrogen morphine derivatives, including morphine-*N*-oxide derivatives, such as codeine-*N*-oxide;

the isomers and stereoisomers of tetrahydrocannabinol;

the ethers, esters and enantiomers of the aforementioned substances, except for dextromethorphan (INN) as an enantiomer of levomethorphan and racemethorphan, and except for dextrophanol (INN) as an enantiomer of levorphanol and racemorphan; [and]

preparations which contain one or more of the above substances.

List II

International non-proprietary name (inn)	Other names	Further description
allobarbitone	-	
alprazolam	-	
amobarbitone	-	
amfepramon	-	
aminorex	-	
barbitone	-	
benzfetamine	-	
bromazepam	-	
brotizolam	-	
buprenorfine	-	
butalbitone	-	
-	butobarbitone	2-bromo-4-(*o*-chlorofenyl)-9-methyl-6*H*-thieno[3,2-*f*]-*s*-triazolo[4,3-*a*][1,4]diazepine
camazepam	-	
cathine	-	
chlordiazepoxide	-	
clobazam	-	
clonazepam	-	
clorazepaat	-	
clotiazepam	-	
cloxazolam	-	
cyclobarbitone	-	
delorazepam	-	
diazepam	-	
estazolam	-	
ethchlorvynol	-	
ethinamaat	-	
ethylloflazepaat	-	
ethylamfetamine	-	
fencamfamine	-	
fendimetrazine	-	
fenobarbitone	-	
fenproporex	-	
fentermine	-	
fludiazepam	-	
flunitrazepam	-	
flurazepam	-	
gluthethimide	-	
halazepam	-	
haloxazolam	-	
	hashish	a normal solid compound of the separated resin obtained from plants of the genus Cannabis (hemp) with vegetable elements of these plants
	hemp	each part of the plant of the genus Cannabis (hemp), from which the resin has not been removed, except for the seeds
-	4-hydroxybutyric acid	
ketazolam	-	
lefetamine	-	
loprazolam	-	
lorazepam	-	
lormetazepam	-	
mazindol	-	

International non-proprietary name (inn)	Other names	Further description
medazepam	-	
mefenorex	-	
meprobamaat	-	
mesocarb	-	
methylfenobarbital	-	
methyprylon	-	
midazolam	-	
nimetazepam	-	
nitrazepam	-	
nordazepam	-	
oxazepam	-	
oxazolam	-	
pemoline	-	
pentazocine	-	
pentobarbital	-	
pinazepam	-	
pipradrol	-	
prazepam	-	
pyrovaleron	-	
secbutabarbitone	-	
temazepam	-	
tetrazepam	-	
triazolam	-	
vinylbital	-	
zolpidem	-	

Preparations containing one or more of the aforementioned substances, except for hempseed oil.

E/NL.2003/36

The Minister of Health, Welfare and Sport

Adopts the following policy guidelines:

1. The Opium Act and Opium Act exemptions

The Opium Act makes it illegal to bring into and outside the territory of the Netherlands, grow, prepare, treat, process, sell, supply, provide, transport, possess and manufacture substances falling under the regime of List I or List II of the Act (Opium Act drugs). Only pharmacists, doctors, dentists and veterinary surgeons may perform certain acts with Opium Act drugs without an exemption within the normal practice of their professions.

Under Article 5, second paragraph, of the Opium Act, some institutions (for example, those providing care for addiction) may also perform certain acts with Opium Act drugs without an exemption insofar as they have been designated by an order in council. An Opium Act exemption is necessary, however, to conduct scientific research (for example, clinical trials). Under Article 6 of the Opium Act, the Minister of Health, Welfare and Sport may grant an application for an exemption to perform one or more acts with Opium Act drugs. In the light of Article 8 of the Opium Act, these exemptions may only be granted for certain purposes and to certain persons or institutions. These policy guidelines have been drawn up with a view to deciding applications for an Opium Act exemption. They further develop the criteria mentioned in the Act which will be applied in the decision on an application for an exemption. They also indicate the restrictions and conditions which may be attached to an exemption. The fees which are associated with obtaining an exemption are also mentioned.

2. Applying for Opium Act exemptions

A distinction is made between, on the one hand, applications for an Opium Act exemption regarding cannabis, cannabis resin or the preparations thereof and, on the other hand, other applications.

Applications for an Opium Act exemption regarding cannabis, cannabis resin or the preparations thereof will be handled by the *Bureau voor Medicinale Cannabis (BMC)* [Office of Medicinal Cannabis], which, since 1 January 2001, has been acting with the authority of a government agency within the meaning of Article 28 in conjunction with Article 23 of the Single Convention on Narcotic Drugs (1961).

To apply for an Opium Act exemption regarding cannabis, cannabis resin or the preparations thereof, a fully completed application form with the requested annexes needs to be sent in. An application form may be obtained from the Ministry of Health, Welfare and Sport, Office of Medicinal Cannabis of the *directie Geneesmiddelen en Medische Technologie (GMT)* [Department of Pharmaceutical Affairs and Medical Technology], Room A-1412, Postbus 20350, 2500 EJ The Hague.

To apply for an Opium Act exemption regarding other Opium Act drugs besides cannabis, cannabis resin or the preparations thereof, an application form may be obtained from the *CIBG* [Central Health Professions Information Centre], Pharmacy Technology Department, Room M-0306, Postbus 16114, 2500 BC The Hague.

If applications are made both regarding cannabis, cannabis resin or the preparations thereof as well as regarding other Opium Act drugs, these will be considered two separate applications, to be handled separately. If granted in such a case, separate Opium Act exemptions will be issued.

3. Purposes for which an Opium Act exemption may be granted

Article 8 of the Opium Act states when an exemption may be granted. This is possible if the applicant has demonstrated:

a. that this will serve the interest of public health or that of the health of animals (article 8, first paragraph, under a);
b. that he needs the exemption to perform scientific or analytical chemical research or for instructional purposes, insofar as the interest of public health does not dictate otherwise (article 8, first paragraph, under b), or
c. that he needs the exemption to bring into or outside the territory of the Netherlands, grow, prepare, treat, process, sell, supply, provide, transport, possess and manufacture Opium Act drugs, and he has an agreement with:
    1. another person who has an exemption;
    2. a pharmacist or a doctor operating a pharmacy;
    3. a veterinary surgeon;
    4. a designated institution or person;
    5. a holder of an exemption granted in another country to import the drugs in question into that country, insofar as the interest of public health does not dictate otherwise (article 8, first paragraph, under c)

An exemption may also be granted if the applicant needs this to grow cannabis pursuant to an agreement with the Minister of Health, Welfare and Sport (see under Point 6).

Of course, the purpose indicated may never be contrary to other laws, regulations or policy guidelines.

4. Criteria attached to the aforementioned purposes

The criteria which will be applied in the decision on an application for an exemption are the following.

Re: 4, under a.

Generally speaking, Opium Act exemptions in the interest of public health or of the health of animals will fall under the general exemption for, for example, doctors, veterinary surgeons, pharmacists or special institutions. Applications for acts with Opium Act drugs may also be filed, however, which do not fall under this exemption, but are nevertheless deemed to be in the interest of public health or that of the health of animals. In that case, an exemption may be granted under this category.

Re: 4, under b.

With regard to an application for an Opium Act exemption to perform scientific or analytical chemical research or for instructional purposes, the necessity of the permit must be demonstrated. In principle, if there are alternative options – that is, the purpose may reasonably be achieved without using Opium Act drugs -, necessity has not been demonstrated.

With regard to an application to perform scientific or analytical chemical research, the purpose must be supported in a scientific manner (for example, through a scientific research protocol for a clinical study or for improving plants).

If applicable, various quality requirements, such as GMP, GLP, GCP or GCLP, or various certification standards (for example, ISO and NEN) must be met. If these cannot be met (or not yet), this has to be supported. If experimental subjects will be involved in the research, a statement must be submitted showing that the experimental design has been reviewed favourably by a competent medical-ethical commission.

A standardised preparation (standardised, for example, regarding one or more of the substances contained) must be used. It must be indicated how the preparation will be prepared and from whom this preparation will be purchased.

The following distinction will apply to applications for instructional purposes:

1. Training dogs to detect narcotics
   Opium Act exemptions to train dogs to detect narcotics will only be granted for detection of narcotics in the Netherlands. Only the police and customs are authorised to engage in these detection activities. They train dogs internally in this regard.
2. Other instructional purposes.

Re: 4, under c.

The commercially-related purposes have been included under c. This provision pertains to, for example, natural or legal persons that trade in Opium Act drugs as a fixed business activity (such as for production or distribution) or to natural or legal persons that wish to conclude a once-only contract to supply an Opium Act drug. Under c, there is a list of those with whom such a contract may be concluded. The possibility is created under 1 to grant exemptions for mutual trade, for example, between traders and researchers. Under 5, the Convention requirement is implemented that an export exemption may only be granted if this is to supply someone in a foreign country who already has an import permit for that country.

5. Growing cannabis

An exemption is necessary under the Opium Act to grow cannabis. BMC is the institution which grants all exemptions regarding cannabis on the Minister's behalf. BMC, which, since 1 January 2001, has been acting as a government agency within the meaning of the Single Convention on Narcotic Drugs, has a monopoly with regard to the import and export of, wholesale trade in, and maintenance of stocks of cannabis and cannabis resin, and must purchase all crops and actually seize these.

BMC's task is two-fold. On the one hand, BMC must research or arrange for research regarding whether cannabis or cannabis products may be used as medicines; on the other hand, BMC must provide pharmacies in the course of 2003 with medicinal cannabis, so that patients can obtain this with a doctor's prescription.

For the first task, developing a medicine, clinical research is not only necessary, but also scientific research into the plant cannabis and into the production process. In the case of scientific research, not only must the criteria referred to in article 8, first paragraph, under b, of the Opium Act, be met, it must also be demonstrated that the research serves a need, given the state of the art.

For the second task, supplying pharmacies, a small number of growers will be approached. In deciding on exemption applications regarding cannabis under Article 8, second paragraph, of the Opium Act, BMC will apply the following criteria. In that case, Article 8i, first paragraph, will be applicable: an exemption will only be granted if BMC concludes a contract to grow and supply cannabis. Thus, growers directly supplying the market will not be granted an exemption to grow cannabis.

In connection with administrative prevention of crime, applicants may be subjected to a security screening, which will include a request to submit administrative and financial data through annual reports with explanations and a so-called Declaration concerning the conduct of the applicant or – in the case of legal persons – of the legal person's directors and actual managers. For a proper evaluation, additional information will have to be provided on request regarding the data supplied. Once the Public Administration Probity in Decision-making Act (the BIBOB Act) has taken effect, probity screening within the meaning of that Act can constitute part of the screening.

If growers apply for an exemption, extensive screening of the applicant will be part of the procedure. In some cases, the Office of Medicinal Cannabis may decide to forego the screening if an application from an institution is involved whose trustworthiness may be assumed beforehand. If necessary, other natural or legal persons involved in the application or in growing the cannabis will be screened as well. This will enable the Office of Medicinal Cannabis to make the risk of cannabis and other Opium Act drugs disappearing to illegal markets as small as possible. The purpose of the screening is to limit the Minister's political risk as much as possible.

All applicants must meet special requirements relating to security around the cannabis, for example, regarding transport and storage. These requirements will be determined on a case-by-case basis and will be recorded contractually.

In addition, BMC will impose special requirements for prospective growers in terms of quality. Hence, the cannabis to be supplied must be produced according to the Regulations for Cultivating Cannabis for Medicinal Purposes (annex), or requirements which are equivalent in BMC's judgment. The Regulations are derived from the Points to Consider on Good Agricultural and Collection Practice for Starting Materials of Herbal Origin (EMEA/HMPWP/31/99 rev. 2) of the Working Group on Herbal Medicinal Products of the European Medicines Evaluation Agency (EMEA). The regulations help ensure that the product's quality is consistent. Depending on the further treatment, the product must also meet other specifications. For example, the production method must guarantee that the product contains a consistent level of active substances.

The prospective grower must also have a quality file for the product. The product characteristics must be carefully recorded in that file. It must include a description of what the growing conditions are (for example, intensity of light, temperature, dampness and fertilisation), what the specifications are of the product grown under these conditions and how there can be monitoring that the product meets these specifications. These requirements regarding composition and the possibility of monitoring are conditions for being able to develop a reproducible medicine. In addition, a prospective grower must be able to demonstrate that he is able to deliver such a standardised product within a reasonable time.

In the event that they are equally suitable, not all prospective growers will obtain an exemption. BMC will compare the growers' offers with each other, with aspects such as the degree to which the requested specifications can be met and the most favourable delivery terms and conditions being decisive, as well as the security which may be provided that none of the cannabis will end up in illegal circuits.

6. Restrictions and conditions in granting an Opium Act exemption

An exemption may be granted which is subject to restrictions. Moreover, conditions may be attached to an exemption. The restrictions and conditions will depend on the nature of the application and may differ in each case. Each Opium Act exemption will include restrictions and conditions regarding the number and type of Opium Act drugs to which the exemption relates, the acts which may be performed, the purpose for which the exemption has been requested, adequate security regarding the Opium Act drugs present, proper records, cooperation with the Health Inspector in monitoring compliance with the exemption and the duration of the exemption.

Additional restrictions and conditions will apply to cannabis growers. For example, growers will be required to sell their entire harvest to BMC. This will be verified by comparing the size of the harvest with the size of the built-up land, the number of plants and through other monitoring measures. This will be further fleshed out in a contract that BMC will conclude with the growers concerned. Another condition that will be imposed on the exemption is that the unnecessary crops be destroyed.

The *Inspectie voor de Gezondheidszorg* [Health Care Inspectorate] will make visits to growers who have received an exemption in connection with monitoring the conditions imposed on the exemption. BMC employees will also visit companies to ensure that there is compliance with the agreed contract terms and conditions.

7 Provisions regarding the exemption for import and export

7.1 Generally

With regard to bringing Opium Act drugs into or outside the territory of the Netherlands (Article 2, under A, and 3, under A, of the Opium Act), an import or export exemption is required. Applications for an import or export exemption will be handled by a special inspector of the Health Care Inspectorate. This inspector will have authority to act for the Minister of Health, Welfare and Sport.

In handling applications for an import and export Opium Act exemption, a distinction will be made between an application regarding an Opium Act drug from List I (Article 2 of the Opium Act) and an application regarding an Opium Act drug from List II (Article 3 of the Opium Act). An exemption will always relate to drugs from either List I or List II; a combined exemption will not be possible. This means that the fee referred to under Point 10 of these policy guidelines will be charged per exemption. An exemption will apply solely to a particular lot or lots of Opium Act drugs as described in the application. The import or export act must be completed within six months after the exemption is granted; if this is not the case, a new exemption will have to be requested.

Applications for an exemption to bring Opium Act drugs into or outside the territory of the Netherlands must be directed to: Health Care Inspectorate, Opium Act Matters Section, Postbus16119, 2500 BC The Hague.

7.2 Data to be provided in connection with import

If the exemption is intended to bring Opium Act drugs into the territory of the Netherlands, the following data must be provided:

- for each drug to be brought into the territory of the Netherlands, the name, the quantity and its pharmaceutical form; if the drug to be imported concerns a preparation with a special name, that name must also be stated;
- for each drug to be brought into the territory of the Netherlands that comes from a country requiring an export document for the export, a copy of that document;
- name and address of the person, including legal persons, outside the Netherlands from whom the drug or drugs will be purchased;
- the time period within which the drug or drugs will be brought into the territory of the Netherlands;
- a statement of the type of transport by which the drug or drugs will be transported to the Netherlands.

7.3 Data to be provided in connection with export

If the exemption is intended to bring Opium Act drugs outside the territory of the Netherlands, the following data must be provided:

- for each drug to be brought outside the territory of the Netherlands, the name, the quantity and its pharmaceutical form; if the drug to be exported concerns a preparation with a special name, that name must also be stated;
- a document issued by the competent government agency in the country to which the drug is to be exported, to the effect that the drug may be imported there;
- name and address of the person, including legal persons, or the government agency outside the Netherlands which will purchase the drug or drugs from the applicant;
- the statement "export to customs warehouse", in the event that storage in a customs warehouse in the country of destination has been approved, as evidenced by a declaration placed on the import document by the competent government agency in the country of destination;
- the time period within which the drug or drugs will be brought outside the territory of the Netherlands;
- a statement of the type of transport by which the drug or drugs will be brought to the country of destination.

8. Varying provisions regarding the exemption for import and export of cannabis and cannabis resin

Varying provisions will apply for the import and export of cannabis and cannabis resin (Article 3, under A). Under Article 8i, fifth paragraph, under a, only the Minister of Health, Welfare and Sport has authority to import and export. This provision means that a person wishing to import or export cannabis or cannabis resin must enter into an import or export agreement with the Office of Medicinal Cannabis, acting on the authority of the Minister. To enter into an import or export agreement with the Office of Medicinal Cannabis, the data mentioned in Section 8.2 or 8.3 must be provided. In connection with this agreement, the fee owed for the import or export (see Point 11) will be passed on. In practice, the person wishing to import or export will already have an Opium Act exemption from the prohibitions of Article 3, under B to D inclusive: preparation, processing, treatment, provision, transport, possession, manufacturing. In such cases no in-depth screening will be conducted.

9. Denial or revocation of Opium Act exemption

An exemption may be denied or revoked. The reasons for denial or revocation are listed in Articles 8b to 8e inclusive of the Opium Act.

10 Fees

Fees will be set by ministerial regulation, the Opium Act Implementation Regulations. The point of departure in calculating the fees incurred to obtain an Opium Act exemption is that the user pays. These fees will be subject to change if the costs related to granting the exemption change. At the time these policy guidelines take effect, a fee of EUR 1225 will be charged to process an application for an exemption or a modification, supplementation or extension thereof, and an annual fee of EUR 350 will be charged during the term of the exemption. In deviation from the foregoing, in the case of an exemption for bringing a drug into or outside the territory of the Netherlands, a fee of EUR 40 will be charged to process an exemption application.

11. Final provision

These policy guidelines shall be cited as: Policy guidelines Opium Act exemptions. These policy guidelines will take effect at the same time that the Act amending the Opium Act (Act of 13 July 2002, *Stb.* [Bulletin of Acts and Decrees] 2002, 520) takes effect.

12 Repeal of earlier policy guidelines

The policy guidelines of 11 May 1998, *Stcrt.* [Government Gazette] 1998, 92, amended on 18 May 2001, Stcrt. 2002, 96 and on 6 December 2001, Stcrt. 2002, 237, are repealed.

The Minister of Health, Welfare and Sport

A.J. De Geus

Annex: Regulations for Cultivating Cannabis for Medicinal Purposes

E/NL.2003/37

In the light of Articles 4, second paragraph, and 7 of the Opium Act

[The Minister of Health, Welfare and Sport]

Decrees:

Section 1
Definitions

Article 1
In this Regulation, the following terms shall have the following meanings:
a. Act: the Opium Act;
b. Opium Act drug: a drug as referred to in List I or List II of the Act;
c. exemption: an exemption as referred to in Article 6 of the Act.

Section 2
Fees

Article 2
1. The fee for processing an application for an exemption from a prohibition as referred to in:
   a. Articles 2, introduction and under B, C or D, and 3, introduction and under B, C or D, of the Act shall be EUR 1225;
   b. Articles 2, introduction and under A, and 3, introduction and under A, of the Act shall be EUR 40.
2. The annual fee for an exemption from a prohibition as referred to in Articles 2, introduction and under B, C or D, and 3, introduction and under B, C or D, of the Act shall be EUR 350.
3. The first paragraph, preamble and under a, shall apply by analogy to an application to extend an exemption from a prohibition as referred to in that provision by five years.

Section 3
Ordering Opium Act Drugs

Article 3
1. An order placed with a pharmacist for an Opium Act drug to be administered in a medical, dental or veterinary practice or in an institution as referred to in Article 16, under c, of the Opium Act Decree shall be written in non-erasable letters and signed by the person placing the order, stating the date of signature. The order shall contain:
   a. the name and initials, the address and the telephone number of the person placing the order;
   b. the name of the particular Opium Act drug as well as, expressed fully in words, the quantity thereof.
2. If a drug is intended for administration in an institution as referred to in Article 16, first paragraph, under c, of the Opium Act Decree, the order shall also contain the name, address and location of the institution as well as the words "for the practice of medicine in", adding the name and address of the institution.
3. If a drug is intended for administration in the practice of the person who issued a prescription for the drug, the order shall also contain the words "for the practice of medicine" or "for the practice of veterinary medicine".
4. For every order for an Opium Act drug placed with a pharmacist, a separate form shall be used.
5. The first to fourth paragraphs inclusive shall not apply to preparations as referred to in Article 8 of the Opium Act Decree.

Section 4
Final Provisions

Article 4
The Import, Export and Transport of Opium Act Drugs Decree and the Prescription of Opium Act Drugs Decree are repealed.

Article 5
This Regulation shall be cited as: 'the Opium Act Implementation Regulations'.

Article 6
This Regulation shall take effect at the time that the Act of 13 July 2002 amending the Opium Act (*Stb.* [Bulletin of Acts and Decrees] 2002, 520) takes effect.

The Minister of Health, Welfare and Sport,

A.J. de Geus

E/NL.2003/38

Explanatory Memorandum

Article 2

In determining the amount of the fee owed pursuant to the first paragraph for processing the application for an exemption from the prohibition to perform one or more of the acts referred to in Articles 2 and 3 of the Opium Act, with the exception of the import or export act, the point of departure used is that the costs of processing a new application fall under the application fee and the costs of modifying existing exemptions, the costs of maintaining the system and the overhead costs have been calculated into the annual fee. Briefly stated, the components of the application fee are the costs of the various stages of processing an application for an exemption by the particular employees of the Ministry of Health, Welfare and Sport. The application costs include the costs of investigations to be conducted by the *Inspectie voor de Gezondheidszorg* [Health Care Inspectorate] in order to assess whether the applicant will meet the requirements imposed by or pursuant to the Opium Act. "Pursuant to the requirements imposed by the Opium Act" also refers to the requirements attached to a permit. The application costs further include all related and ensuing administrative costs and the costs of applying for and obtain an advisory opinion from the Office referred to in Article 9 of the Public Administration Probity in Decision-making Act, the so-called BIBOB Office.

The same fee that is charged for a new application will apply to an application to extend an exemption for the maximum term.

Briefly stated, the components of the annual fee are the costs of:

- managing the computerised system;
- consulting with the relevant departments of the Ministry of Health, Welfare and Sport, such as the Office of Medicinal Cannabis and the Health Care Inspectorate;
- calculating and collecting the annual fee and processing changes;
- developing standard letters;
- legal and administrative support;
- accommodation and other overhead.
-

The number of changes for each exemption is calculated by dividing the average number of changes for each year by the average number of exemptions for each year.

Before the present Regulation took effect, a differentiated system of fees applied. What was determinative was the nature of the act for which an exemption was requested and the locations where that act was performed. That system has been abandoned. The new system is based on the average costs for each type of act. For that matter, it is rarely the case that an exemption is requested to perform only one type of act. A combination of acts is nearly always involved.

It follows from the second paragraph that no annual fee will be owed for administering the exemptions granted for import and export. That is related to the provision in Article 7 of the Opium Act that the import and export exemption in each case – that is, for a certain lot of medicines containing Opium Act drugs or a certain lot of Opium Act drugs as such – will be granted for at most six months.

The amount of EUR 40 takes into account the costs of administratively processing the application and the decision (personnel plus overhead) and the costs of assessing and deciding the application. In the Opium Licences Decree which is to be repealed and which dates from October 1976 and was last amended in 1995, the fee for an import or export licence was set at NLG 70. That amount has not changed since 1995. The amount of the fee set forth in the present Regulation (EUR 40) is determined to be NLG 70, converted into euros and adjusted for inflation over the past seven years.

The amounts included here were included before the legislative amendment in the Decree Containing Rules regarding Fees for Opium Licences.

Article 3

The first three paragraphs of this Article include the content of Article 7 of the Prescription and Ordering of Opium Act Drugs Decree. Pursuant to the relevant delegation provisions of the Opium Act, the content of that Decree has been divided between the Opium Act Decree, regulating the prescribing of Opium Act drugs, and the present Regulation, regulating the ordering of Opium Act drugs.

Paragraph 4 provides that every order placed with pharmacists as referred to in the fourth paragraph of this Article must be made with a separate form. This provision is a consequence of the risky nature of the drugs and, in particular, the carelessness seen by the Health Care Inspector in the past. That makes it necessary to build in good monitoring possibilities. Registration for each order is an aspect of this. For prescriptions, these extra monitoring possibilities have been built in through imposing additional rules in the Opium Act Decree, entailing that prescriptions, arranged successively by the name of the person issuing the prescription, the name of the substance and the date of supply, must be kept. More generally, Article 7 of the Opium Act Decree also contains strict administrative provisions, including the authority of the Health Care Inspector to provide further instructions.

The present Regulation is based on Article 4, second paragraph, of the Opium Act and is less stringent than the provisions applicable to registration of prescriptions, contained in Article 5, first paragraph, of the Opium Act Decree. Substantively, the old regulation is not being changed, so that there is no change in the administrative burden.

Article 4

The content of the ministerial regulation Import, Export and Transport of Opium Act Drugs Decree will be part of the conditions which will be attached to an import or export exemption under Article 8a, first paragraph, of the Opium Act. That ministerial regulation must therefore be repealed. The present Article provides for this.

In the amendment of the Opium Act by the Act of 16 December 1998 (*Stb.* 1999, 10), Article 4, first paragraph, of the Opium Act was amended in such a manner that the statutory basis for the ministerial regulation Prescription of Opium Act Drugs Decree disappeared and no longer was applicable as a result. This was pointed out in the general part of the Explanatory Memorandum to the Prescription and Ordering of Opium Act Drugs Decree. The content of that ministerial regulation was included in the Prescription and Ordering of Opium Act Drugs Decree. That Decree is being repealed by the Opium Act Decree.

Because the ministerial regulation was never formally repealed, it did not sufficiently become known that that regulation was no longer applicable. In order to remove any doubt in this respect, the present Regulation formally repeals the Prescription of Opium Act Drugs Decree.

The *adviescollege toetsing administratieve lasten (Actal)* [Advisory Board on Administrative Burden] decided in its meeting of 21 November 2002 not to select the present Decree for an Actal test of the consequences for businesses in terms of administrative burden.

The Minister of Health, Welfare and Sport,

A.J. de Geus

E/NL.2003/39

Decree of 9 December 2002 Containing Implementation Rules Pursuant to The Opium Act (Opium Act Decree)

At the recommendation of Our Minister of Health, Welfare and Sport of 2 October 2002, No. 02.004519, made in accordance with Our Minister of Justice and the State Secretary for Agriculture, Nature Management and Fisheries;

In the light of Articles 3c, 4, first paragraph, and 5, first and second paragraph, of the Opium Act;

After having heard the advice of the Council of State (Advisory Opinion of 24 October 2002, No. W13.02.0425/III);

Given the further report of Our Minister of Health, Welfare and Sport of 9 December 2002, made in accordance with Our Minister of Justice and the State Secretary for Agriculture, Nature Management and Fisheries;

Have approved and decreed:

Chapter 1
Definitions

Article 1

In this Decree, the following terms shall have the following definitions:

a. 'Act': the Opium Act;
b. 'Chief Inspector': the Chief Inspector for Pharmacy and Medical Technology;
c. 'Regional Inspector': the Inspector for Public Health in Regional Service, with the portfolio Pharmacy;
d. 'Opium Act drug': a drug to which Article 2 or Article 3 of the Act applies;
e. 'prescription': a written instruction as referred to in Article 1, first paragraph, under I, of the Medicines Act or Article 1 of the Veterinary Medicines Act;
f. 'doctor operating a pharmacy': a doctor who is authorised to prepare medicines under Article 6 of the Medicines Act;
g. Practising pharmacist: a pharmacist who is registered in the Register of Practising Pharmacists, as referred to in **A**rticle 14 of the Medicines Act.

Chapter 2
Prescribing of Opium Act drugs

Article 2

1. It shall be illegal to issue a prescription for other Opium Act drugs besides those referred to in the Annex to this Decree, unless these are prescribed for experimental subjects in connection with research within the meaning of the Medical Research Human Subjects Act or for animals in connection with research within the meaning of the Animal Experiments Act.
2. Other Opium Act drugs besides those referred to in the Annex to this Decree shall only be used or administered in an institution as referred to in Article 16, or in the practice of a person prescribing such a drug in connection with research as referred to in the first paragraph, on the understanding that such drugs shall only be administered or used in connection with research within the meaning of the Animal Experiments Act by the licence holder within the meaning of that Act.

Article 3

1. A separate prescription shall be issued for each Opium Act drug to be prescribed.
2. A prescription for an Opium Act drug shall be written and signed in indelible letters by the person issuing the prescription, stating the date of signing. The prescription shall contain:
   a. the name and initials, address, city and telephone number of the person issuing the prescription;
   b. the name of the Opium Act drug prescribed as well as the quantity thereof, written in full in letters.
3. If a prescription is for the purpose of supplying an Opium Act drug to a person for whom or for whose animal the Opium Act drug is being prescribed, the prescription shall also contain:
   a. the name and initials, address and city of that person and, insofar as the prescription relates to an animal, a description of the animal;
   b. a clear description of the manner of use, including the maximum amount to be used in a 24-hour period;
   c. the permissible number of repeats, written in full in letters.
4. If an Opium Act drug is prescribed for a person or an animal, but is supplied through the person issuing the prescription, the prescription shall contain, in addition to the information referred to in the second paragraph and the third paragraph, under a, the words *'in manu medici*' or other words to the same effect.

Chapter 3
Supply of Opium Act drugs by prescription

Article 4

1. Pharmacists shall only supply Opium Act drugs by a prescription as referred to in Article 3, second paragraph, or by an order which complies with the provisions of or pursuant to Article 4, second paragraph, of the Act.
2. The first paragraph shall not apply in cases in which supply cannot be delayed and the pharmacist may reasonably assume that there is no risk of abuse.
3. Doctors operating pharmacies shall only supply Opium Act drugs for persons who are part of their medical practice by a prescription as referred to in Article 3, second paragraph.

Article 5

1. Practising pharmacists and doctors operating pharmacies shall save the prescriptions by which an Opium Act drug has been supplied for at least six years, separately from the other prescriptions in the pharmacy and arranged successively by the name of the person issuing the prescription, the name of the substance and the date of supply. If the prescription relates to a preparation containing more than one substance, as many copies of it shall be made as there are substances.
2. During the period referred to in the first paragraph, the prescriptions referred to in that paragraph shall be kept at the Regional Inspector's disposal by practising pharmacists and doctors operating pharmacies.
3. Practising pharmacists shall send copies of prescriptions as referred to in the first paragraph which pertain to cases in which an Opium Act drug has been supplied in any quarter to the person who prescribed it or to an institution as referred to in Article 16 to the Regional Inspector on the first day of the next quarter.

Article 6

1. Practising pharmacists, doctors operating pharmacies and veterinary surgeons shall only take delivery of a quantity of an Opium Act drug on submission of an acknowledgment of receipt, a copy of which they shall keep. In the event the drug was sent by post, the acknowledgment of receipt shall be sent to the person delivering the drug within three days, Saturdays, Sundays and recognised public holidays not included, after the date of receipt.
2. The acknowledgment of receipt, which shall be signed and dated by the practising pharmacist, the doctor operating the pharmacy, the veterinary surgeon or by a person authorised in this regard by him, shall contain:
   1. the name and address of the practising pharmacist, the doctor operating the pharmacy or the veterinary surgeon;
   2. the name and the quantity of the Opium Act drug, as well as the medicinal form, in the event it concerns a preparation;
   3. the name and address of the person supplying the drug.

3. The name of the person signing must be written in a clearly legible manner under the signature of the acknowledgment of receipt.
4. Practising pharmacists, doctors operating pharmacies and veterinary surgeons shall verify within three days, Saturdays, Sundays and recognised public holidays not included, after the date of receipt of a quantity of a drug whether what has been delivered to them is consistent with what has been stated in this regard in the acknowledgment of receipt. If there is no such consistency, they shall notify the person who supplied the drug within the time period referred to in the first sentence. They shall keep a copy of the written notification. If the Opium Act drug was sent by post, the acknowledgment of receipt shall be sent unsigned with the written notification.
5. Practising pharmacists, doctors operating pharmacies and veterinary surgeons shall keep the copies referred to in the first paragraph separate from other acknowledgments of receipt and by name of the drug, in chronological order according to the date of receipt for at least six years, and shall keep them at the Regional Inspector's disposal during that period.
   If there has been written notification as referred to in the fourth paragraph, they shall keep a copy of this with the copy of the acknowledgement of receipt to which the notification pertains.

Article 7

1. Practising pharmacists, doctors operating pharmacies and veterinary surgeons shall keep records concerning the receipt, origin, destination, supply, administration, loss and destruction, as well as treatment or processing of Opium Act drugs.
2. The records shall separately state for each Opium Act drug the information referred to in the first paragraph.
3. The records shall be set up in such a manner that it shall be possible to deduce easily from them at any time how much of an Opium Act drug is in stock.
4. The Regional Inspector may give instructions regarding setting up the records. The persons referred to in the first paragraph shall be obliged to comply with such instructions.
5. The records shall be saved for six years and kept at the disposal of the Regional Inspector during that period.

Article 8

1. Articles 3, 4, 5, 6 and 7 shall not apply to preparations which do not contain any other substances besides those referred to in List II accompanying the Act, except for the substances:
   amobarbital
   buprenorphine
   butalbital
   cathine
   cyclobarbital
   flunitrazepam
   gluthetimide
   hemp
   pentazocine and
   pentobarbital
2. The Articles referred to in the first paragraph shall also not apply to:
   a. preparations of:
      acetyldihydrocodeine;
      codeine,
      dihydrocodeine,
      ethyl morphine,
      pholcodine,
      nicocodine,
      nicodicodine,norcodeine or
      insofar as the preparation contains one or more other components and does not contain more than 100 mg of the aforementioned substance per dosage unit, or, in the event of an undivided preparation, the concentration of that substance in the preparation does not exceed 2.5 percent;
   b. preparations of propiram which do not contain more than 100 mg of propiram per dosage unit and to which at least an equivalent quantity of methylcellulose has been added;

c. preparations of dextropropoxyphene for oral use which do not contain more than 135 mg of dextropropoxyphene base per dosage unit or in which, in the event of an undivided preparation, the concentration of that substance does not exceed 2.5 percent;
d. preparations of cocaine which do not contain more than 0.1 percent cocaine, calculated as a base, and preparations of opium or morphine which do not contain more than 0.2 percent morphine, calculated as an anhydrous base, insofar as those preparations have been composed in such a way that the substances in question cannot be recovered easily or in such amounts that this poses a public health risk;
e. preparations of diphenoxine which do not contain more than 0.5 mg of diphenoxine per dosage unit as well as a quantity of atropine sulphate of at least 5 percent of the quantity of diphenoxine;
f. preparations of diphenoxylate which do not contain more than 2.5 mg of diphenoxylate per dosage unit, calculated as a base, as well as a quantity of atropine sulphate of at least 1 percent of the quantity of diphenoxylate;
g. pulvis ipecacuanhae et opii compositus, consisting of: 10 percent opium in powder form, 10 percent ipecacuanha root in powder form, blended properly with 80 percent of another component in powder form which does not contain a drug as referred to in Article 2 or 3 of the Act;
h. mixtures of the preparations as referred to under a to g inclusive with any material that does not contain a drug as referred to in Article 2 or 3 of the Act.

3. Pharmacists and doctors operating pharmacies shall only supply the preparations referred to in the first and second paragraph by prescription.

Chapter 4
Registration of administration of Opium Act drugs

Article 9

1. A doctor who, in the Regional Inspector's judgment, does not sufficiently demonstrate that he needed Opium Act drugs in the quantity found in his possession to practise medicine shall, after a written instruction to this effect by the Chief Inspector, record every administration in a register exclusively intended for this purpose. This register shall be set up and maintained to the Regional Instruction's satisfaction, stating:
   a. the name and the quantity of the Opium Act drug administered;
   b. the name and initials, as well as the address and city of the person to whom the Opium Act drug was administered;
   c. the date of administration.
2. An instruction as referred to in the first paragraph shall apply for at most three years and shall state the period for which it applies.
3. Upon request, the doctor shall provide the register referred to in the first paragraph for the Regional Inspector's examination.

Chapter 5
Excluded drugs and applications

Article 10

The prohibitions stated in Article 2, introduction and under B and C, of the Act shall not apply to:

a. possessing, transporting and threshing poppy straw which is intended to be destroyed at the threshing location after threshing;
b. possessing, threshing, selling, supplying and transporting poppy straw which is intended to be supplied to the holder of an exemption as referred to in Article 6, first paragraph, of the Act, for manufacturing opium alkaloids;
c. treating, selling, supplying, transporting and possessing the fruits of poppy straw, whether or not stemmed, which are intended to be used as decoration.

Article 11
The prohibitions stated in Article 2, introduction and under B and C, of the Act shall not apply to preparations which contain at most 0.5 mg of codeine per gram or per millilitre and do not contain any of the other substances stated on List I accompanying the Act.

Article 12
The prohibitions stated in Article 3, introduction and under B, of the Act shall not apply to hemp which is clearly intended to recover fibre or to multiply seeds for the production of fibre hemp, on the understanding that the exception from the prohibition on growing hemp shall only apply insofar as the hemp is not grown in pots and is grown in the open air.

Article 13
The prohibition on possession, treatment or processing stated in Article 3, introduction and under B and C, of the Act shall not apply to barbital or a preparation containing barbital, insofar as clearly intended for analytical chemical purposes.

Article 14
The prohibition stated in Articles 2, introduction and under A, and 3, introduction and under A, of the Act, as well as the prohibition on possession, treatment or transport stated in Articles 2, introduction and under B and C, and 3, introduction and under B and C, of the Act shall not apply to diagnostic material to investigate and identify drugs to which the Act pertains, if the concentration of each of the Opium Act drugs present in the material does not exceed 0.01%.

Article 15
The prohibition stated in Articles 2, introduction and under A, and 3, introduction and under A, of the Act, as well as the prohibition on possession, transport, sale, supply and provision stated in Articles 2, introduction and under B and C, and 3, introduction and under B and C, of the Act, shall not apply if a homeopathic medicinal product is involved within the meaning of the Homeopathic Medicinal Products Decree which contains a drug to which the Act pertains, the medicinal form of that product does not have a concentration of the drug higher than one-millionth of the original tincture and, in the packaging in which the product is marketed, not more than 1 microgram of the drug is present.

Chapter 6
Designated institutions

Article 16
The prohibitions, insofar as relating to provision and transport, stated in Articles 2, introduction and under B, and 3, introduction and under B, of the Act and the prohibitions stated in Articles 2, under C, and 3, under C, of the Act, shall not be applicable to:
a. hospitals within the meaning of the Medicines Act;
b. Working Conditions Services within the meaning of the Working Conditions Act 1998 and in-house emergency and first aid service as referred to in Article 15 of that Act, insofar as Opium Act drugs designated by Our Minister are involved;
c. institutions permitted under the Exceptional Medical Expenses Act to render assistance to addicts, insofar as Opium Act drugs designated by Our Minister are involved;
d. institutions as referred to in the Prisons Act, institutions as referred to in the Hospital Orders Act and institutions as referred to in the Youth Custodial Institutions Act;
e. the Organisation for the Prohibition of Chemical Weapons.

Chapter 7
Transitional and final provisions

Article 17
Article 63, under b, of the Medicinal Products Decree is repealed. Part c is re-lettered part b"

Article 18
The following decrees are repealed:
- the Royal Decree of 18 October 1976 Implementing Article 3a, first paragraph, of the Opium Act (*Bulletin of Acts and Decrees* 1976, 509);
- the Royal Decree of 18 October 1976 Designating Institutions, referred to in Article 16, third paragraph, of the Opium Act (*Bulletin of Acts and Decrees* 1976, 512);
- the Royal Decree of 18 October 1976 Containing Rules regarding Registration of the Administration of Opium Act Drugs (*Bulletin of Acts and Decrees* 1976, 510);
- the Opium Licences Decree;
- the Prescription and Ordering of Opium Act Drugs Decree;
- the Supply on Prescription of Opium Act Drugs Decree;
- the Designation 2-CB Decree;
- the Royal Decree of 6 December 1996 Designating Several Drugs under Article 2, Second Paragraph, of the Opium Act as well as Amending List II Accompanying the Opium Act (*Bulletin of Acts and Decrees* 1996, 634);
- the Royal Decree of 19 January 2000 Designating Drugs under Article 2, Second Paragraph, of the Opium Act and Amending Another Decree (*Bulletin of Acts and Decrees* 2000, 41);
- the Royal Decree of 28 July 2002 Designating Drugs under Article 2, Second Paragraph, of the Opium Act as well as Amending List II Accompanying the Opium Act under Article 3, Second Paragraph, of that Act (*Bulletin of Acts and Decrees* 2000, 438);.

Article 19
In Article 5, first paragraph, "for at least six years" shall be repealed at the time that the legislative proposal to amend Chapter III of the Medicines Act and Part 5 of Title 7 of Book 7 of the Dutch Civil Code, submitted through the Royal Message of 26 July 2002 (*Parliamentary Documents II*, 2001-2002, No. 28 494), takes effect after being enacted.

Article 20
This Decree shall be cited as: 'the Opium Act Decree'.

Article 21
If the legislative proposal to amend the Opium Act, submitted through the Royal Message of 13 July 2001 (*Bulletin of Acts and Decrees* 2000, 520), takes effect after being enacted, this Decree shall become effective at the same time.

We hereby order and command that this Decree be published in the *Bulletin of Acts and Decrees* and the accompanying Explanatory Memorandum.

Signed at The Hague, 9 December 2002

Beatrix

Annex Accompanying the Opium Act Decree

a. The following drugs stated on List I:
acetylmethadol
alfacetylmethadol
alfentanil
amphetamine
amobarbital
bezitramide
buprenorphine
butalbital
cocaine
codeine
cyclobarbital
dexamphetamine
dextromoramide
dextropropoxyphene
diphenoxylate
dihydrocodeine
ethyl morphine
fentanyl
flunitrazepam
hydrocodone
hydromorphone
4-hydroxy butyrate
metamphetamine
metamphetamine racemate
methadone
methylphenidate
morphine
nicomorphine
opium
oxycodone
pentazocine
pentobarbital
pethidine
piritramide
remifentanil
secobarbital
sufentanil
Δ-9-tetrahydrocannabinol

b. the drugs stated in List II of the Opium Act, except for hashish,

c. the salts, esters, ethers and enantiomers of the aforementioned substances,

d. preparations of the aforementioned Opium Act drugs, insofar as they do not contain any Opium Act drugs which are not referred to in this Annex.

E/NL.2003/40

Guidelines for cultivating cannabis for medicinal purposes

Annex to the Regulation of the Minister of Health, Welfare and Sport of 9 January 2003, GMT/BMC 2340685, containing policy guidelines for the decision on applications for Opium Act exemptions (Policy guidelines Opium Act exemptions)

1. Introduction

Under certain conditions, the Dutch government permits the cultivation of cannabis for medicinal purposes. In the case of herbal drugs, the cultivation method and primary processing of the plant determines the ultimate properties of the active pharmaceutical ingredient. Starting materials of herbal origin have a complex composition and can only be characterised to a limited extent through chemical or biological analysis. Therefore, an effective quality assurance system in the steps leading up to the production of the active pharmaceutical ingredient is needed in order to guarantee reproducible quality. These steps are cultivation, harvesting and primary processing.

The following guidelines for cultivating, harvesting and primary processing of cannabis constitute a quality assurance system that meets these requirements. The Office of Medicinal Cannabis (Bureau voor Medicinale Cannabis) will test on the basis of these requirements.

These guidelines have been derived from the general rules for Good Agricultural Practice of the Working Group on Herbal Medicinal Products of the European Medicines Evaluation Agency (EMEA).

This is a non-authorised translation of the official version in Dutch.

2. General

2.1. These guidelines apply to the cultivation, harvesting and primary processing of cannabis plants intended for medicinal use or the preparation of medicinal drugs. These guidelines must be read in connection with the European Good Manufacturing Practice (GMP) guidelines for active pharmaceutical products. They apply to all methods of production including organic cultivation. These guidelines also provide additional standards for the production and processing of herbal starting materials insofar as they identify the critical production steps that are needed to ensure good, reproducible quality.

2.2. The main objective of these guidelines is to increase the reliability of the medicines prepared from cannabis by establishing an appropriate quality standard for the herbal medicine cannabis. In particular, it is important that the cannabis:
- is produced hygienically to keep microbiological contamination to a minimum;
- is produced such that negative effects on the plants during cultivation, processing and storage are kept to a minimum;
- is produced under conditions that ensure that the therapeutic properties of the end product are constant and reproducible.

3. Personnel and training

3.1 Training

3.1.1 Personnel must have received adequate botanical/horticultural training before performing the tasks given to them.

3.1.2 Production personnel must be trained in the production techniques used.

3.1.3 Primary processing procedures must comply with the regulations on food hygiene.

3.2 Hygiene

3.2.1 All personnel entrusted with handling the herbal material must maintain proper personal hygiene.

3.2.2 Persons suffering from infectious diseases transmittable via food, including diarrhoea, or carriers of these diseases must be forbidden access to areas where they could come into contact with the herbal material.

3.2.3 Persons with open wounds, inflammations and skin-infections must be suspended from areas where they could come into contact with herbal material, unless they wear protective clothing or gloves until they have recovered completely.

3.2.4 Personnel must be protected from contact with toxic or potentially allergenic herbal material by means of adequate protective clothing.

4. Buildings and facilities

4.1 Rooms used in the processing of harvested crops must be clean, well ventilated and must never be used for other activities.

4.2 Buildings must be designed in a manner that protects the crops against pests and domestic animals.

4.3 The medicinal cannabis must be stored:
- in a suitable packaging
- in rooms with concrete or similar floors which are easy to clean;
- on pallets;
- at a sufficient distance from walls;
- well separated from other crops in order to prevent cross-contamination.

Organic products must be stored separately from products not grown organically.

4.4 Buildings where plant processing is carried out must have changing facilities, toilets and hand-washing facilities.

5. Equipment

5.1 Equipment used in plant cultivation and processing must be easy to clean in order to eliminate the risk of contamination.

5.2 Equipment and machinery should be mounted such that they are easily accessible. Machines used in fertiliser and pesticide application must be calibrated regularly.

5.3 The equipment must be made from materials other than wood. If wooden materials (such as pallets) are used, they must not come into direct contact with chemicals and contaminated materials, in order to prevent contamination of the herbal materials.

5.4 Equipment and machinery used for harvesting must be clean and in very good working condition. Machine parts that come into direct contact with the harvested crop must be cleaned regularly and must be free from oil and contamination, including residual plant matter.

6. Seeds and propagation material

6.1 Seeds and propagation material must be botanically identified as to species, variety, chemotype and origin. The materials used must be traceable. Starting material must be free from pests and disease as much as possible in order to guarantee healthy growth.

6.2 Cuttings of female plants must be used as propagation material for the production of cannabis.

6.3 During the entire production process (cultivation, harvest, drying, packaging), the presence of male plants and of different species, different varieties or different plant parts must be monitored. Any impurities must be removed immediately.

7. Cultivation

7.1 Soil and fertilisation

7.1.1 Cannabis for medicinal purposes must not be grown on soil contaminated with sludge, heavy metals, pesticide residues or other chemicals. Any chemicals used must therefore be kept to the minimum effective dose.

7.1.2 Manure applied should be thoroughly composted and must be devoid of human faeces. Irrigation should be controlled and according to the needs of the cannabis plant. Fertilisers should be used in such a way that leaching is reduced to a minimum.

7.2 Irrigation

7.2.1 Irrigation must be controlled and only as required by the cannabis plant.

7.2.2 Irrigation water must contain as few as possible contaminants like faeces, heavy metals, pesticides and toxicologically hazardous substances.

7.3 All tillage must be adapted to plant growth and requirements. Using herbicides and pesticides must be avoided as far as possible. Use and storage of pesticides must be in accordance with the recommendations of the manufacturer and the relevant approval authorities. Only qualified personnel are allowed to use such substances using only approved material but not in a period preceding the harvest, as indicated by the buyer or producer.

8. Harvesting

8.1 Harvesting must be done when the plants have reached the best quality for the intended use.

8.2 Damaged, and dead plants must be removed.

8.3 Harvesting must take place under the best possible conditions, avoiding wet soil or extremely high air humidity. If harvesting occurs in wet conditions, additional care needs to be taken to avoid the adverse effects of moisture.

8.4 During harvesting, care must be taken that no other species or cannabis variety gets mixed with the crop.

8.5 The harvested crop must not come into direct contact with the soil. Directly after harvesting, it must be prepared for transport in clean, dry conditions (e.g. sacks, baskets, boxes).

8.6 All containers must be clean and free from any residues from previous harvests; containers that are not in use must be kept in dry conditions, free of pests and inaccessible to domestic animals.

8.7 Mechanical damage and compacting of the herbal drug that could result in undesirable quality changes must be avoided. In this respect, take care to avoid:
- overfilling sacks/containers;
- stacking sacks/containers too high.

8.8 Freshly harvested herbal material must be delivered to the processing facility as quickly as possible in order to prevent thermal degradation.

8.9 The harvested crop must be protected from pests and domestic animals.

9. Primary processing

9.1 Primary processing includes washing, cutting before drying, freezing, distillation, drying, etc.

9.2 On arrival at the processing facility, the harvested crop must be directly unloaded and unpacked. Prior to processing, the material must not be exposed to direct sunlight (except in cases that specifically require this) and must be protected from rain.

9.3 Drying

9.3.1 Drying crops directly on the ground or under direct sunlight must be avoided.

9.3.2 Uniform drying speed and prevention of mold growth must be assured.

9.3.3 In the case that plant material is dried in the open are, it must be spread in a thin layer. To ensure good air circulation the drying racks must be placed at sufficient distance to the floor.

9.3. 4In the case plant material is not dried in the open air optimal drying circumstances like temperature and drying time must be chosen.

9.4 Waste bins must be available and must be emptied and cleaned daily. Waste must be collected in bags and/or in closable containers.

10. Packaging

10.1 Following repeated controls and removal of any material not meeting its requirements or of undesired objects, the product must be packaged in clean, dry and preferably new packaging. The label must be clear, firmly fixed and made from non-toxic material.

10.2 Reusable packaging material must be well cleaned and dried prior to use.

10.3 Packaging material must be stored in a clean, dry place that is free of pests and inaccessible to domestic animals. The packaging material must not contaminate the product.

11. Storage and distribution

11.1 Dried, packaged products and extracts must be stored in a dry, well-ventilated room in which daily temperature fluctuations are limited and good ventilation is ensured. Fresh products must be stored between 1°C and 5°C; frozen products must be kept at temperatures below -18°C (or below -20°C for long-term storage).

11.2 In the event of bulk transport, it is important to ensure dry conditions. To prevent mould formation or fermentation, it is advisable to use ventilated containers, transport vehicles and other ventilated facilities.

11.3 Decontamination of the storage area to combat pests must be carried out only where necessary and by authorised personnel only.

11.4 When frozen storage or saturated steam is used for pest control, the moisture content of the product must be controlled after treatment.

12. Special provisions for the production of cannabis intended for processing into a standardised herbal drug.

12.1 Herbs

a. In these guidelines a herbal medicine is understood to mean any medicine that contains exclusively herbal drugs or herbal preparations as active ingredients.
b. Herbal drugs are plants or parts of plants in an unprocessed state which are used for medicinal or pharmaceutical purposes. A herbal drug or a preparation is regarded as one active substance in its entirety whether or not the constituents with therapeutic activity are known.
c. Herbal drug preparations are comminuted or powdered herbal drugs, extracts, tinctures, fatty or essential oils, expressed juices, processed resins or gums, etc. prepared from herbal drugs, and preparations that are produced through fractionation, purification or concentration.
d. In departure from the above, chemically defined isolated constituents or their mixtures are not considered herbal drug preparations.
e. Herbal drug preparations may contain other components such as solvents, diluents and preservatives.

12.2 If the cannabis is intended for processing into a standardised herbal medicine, the cannabis must be cultivated under such standardised conditions that the content of the constituents is constant. Protocols of the operations committed during the cultivation must be kept available.

12.3 The content of the main constituents, which includes Δ-9-tetrahydrocannabinol (Δ-9-THC) and cannabidiol (CBD), is determined quantitatively. For a selection of the other constituents, fingerprinting with a suitable technique, such as GC-MS, GC, HPLC or TLC will suffice.

12.4 Unless it is proven that omitting the standardisation of one of the following elements results in a constant and reproducible product, at least the following must be standardised during cultivation:

a. cultivation of the cannabis plant;
b. cultivation substrate;
c. day length;
d. light intensity;
e. colour temperature of the lighting;
f. atmospheric humidity;
g. temperature;
h. irrigation
i. ventilation;
j. plant age at the time of harvesting;
k. time of day of harvesting.

12.5 Unless it is proven that omitting the standardisation of one of the following elements results in a constant and reproducible product, at least the following must be standardised during drying:

a. atmospheric humidity;
b. temperature;
c. ventilation;

drying time.

13. Documentation

13.1 All processes and procedures which may affect the quality of the product must be recorded in the documentation for each batch. The following in particular must documented:

b. the location of cultivation and the name of the cultivator in charge;
c. details on crops previously grown at that location;
d. nature, origin and quantity of the herbal starting materials;
e. the chemicals and other substances used during cultivation, such as fertilisers, pesticides and herbicides;
f. standard cultivation conditions, if applicable;
g. particular circumstances which occurred during cultivation, harvesting and production which may affect the chemical composition, such as plant diseases or temporary departure from standard cultivation conditions, particularly during the harvesting period;
h. nature and quantity of the yield;
i. date or dates, and time or times of day when harvesting occurred;
j. drying conditions;
k. measures for pest control.

13.2 Analysis reports of soil analysis must be kept available in the dossier

13.3 Location

13.3.1 All batches originating from one location must be clearly labelled (e.g. with a batch number). This must be done as early on in the process as possible.

13.2.2 Batches originating from different geographic locations may only be combined if guaranteed to be the same, and that the mixture is homogenous. Mixing of batches must be documented.

13.3 It must be recorded in the documentation for each batch that the cultivation, harvest and primary processing procedures were in accordance with these requirements.

13.4 All parties involved in the production process must demand that their suppliers document all relevant stages and elements of the production process for each batch.

13.5 Audit results must be recorded in an audit report. The audit report and concomitant analysis reports and other documents must be kept for at least ten years.

14. Safeguarding the material

14.1 The buildings in which the cannabis is cultivated, processed, packaged and stored must be sufficiently secured. This means that there must be security in force and that only authorised personnel is allowed access to the buildings.

14.2 The personnel involved in the production process of cannabis must be authorised for that purpose by the employer. When concluding the supply contract, the supplier designates authorised persons and indicates how this will be verified.

14.3 There must be a balanced administration of the cannabis.

14.4 Waste must be stored in such a way that theft is impossible. If waste is collected in bags it must be stored in a lockable container (for instance a pressing container) immediately.