Decree of

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 … November 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, …… 2002,

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The Minister of Health,
Welfare and Sport

Annex Accompanying the Opium Act Decree

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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.