

UNITED NATIONS

E/NL. 1957/97 25 September 1957 ENGLISH Original: ITALIAN

LAWS AND REGULATIONS

PROMULGATED TO GIVE EFFECT TO THE PROVISIONS OF THE CONVENTION OF 13 JULY 1931 FOR LIMITING THE MANUFACTURE AND REGULATING THE DISTRIBUTION OF NARCOTIC DRUGS, AS AMENDED BY THE PROTOCOL OF 11 DECEMBER 1946

ITALY

Communicated by the Government of Italy

NOTE BY THE SECRETARY-GENERAL -- In accordance with Article 21 of the Convention of 13 July 1931 for Limiting the Manufacture and Regulating the Distribution of Narcotic Drugs, as amended by the Protocol of 11 December 1946, the Secretary-General has the honour to communicate the following legislative text.

DECREE OF THE HIGH COMMISSIONER FOR HYGIENE AND PUBLIC HEALTH

9 JANUARY 1957

LIST OF SUBSTANCES AND PREPARATIONS COMING UNDER THE PROVISIONS OF NARCOTIC DRUGS LEGISLATION

The High Commissioner for Public Health and Sanitation Having Regard to the need to bring the list of narcotic drugs up to date;

Having Regard to the need to bring the fist of natcotte drugs up to

Having Consulted the Supreme Council of Health;

In Pursuance of article 3 of Act No. 1041 of 22 October 1954¹⁾;

HEREBY DECREES THAT:

The following list of substances and preparations coming under the provisions of narcotic drugs legislation is approved:

GROUP A

1. Opium and its preparations. Exceptions: preparations not for parenteral use, having an equivalent basic morphine content not exceeding 0.05%;

- (a) Dover's powder; and
- (b) Tincture of opium and Sydenham laudanum, only when supplied in an emergency, in an amount not exceeding 2 g. and for immediate use on the premises. Pharmacists shall record monthly in their prescription register the amounts so supplied.

2. Poppy straw used for the production of drugs or preparations which must be considered narcotic drugs.

3. Coca leaves and all preparations thereof having an equivalent cocaine content exceeding 0.03%.

1) Note by the Secretariat: E/NL.1954/144,

4. Indian hemp /cannabis/ (hashish, marijuana, etc.) and all its preparations the Indian hemp content of which equals or exceeds 0.1%.

5. Mixed alkaloids of opium and salts and preparations thereof.

6. Morphine and its salts and preparations. Exceptions: preparations having an equivalent basic morphine content not exceeding 0.05%, other than preparations for parenteral use and solutions and dilutions of morphine in a solid or liquid inert substance.

7. Diacetylmorphine (diamorphine) and its salts (hydrochloride: heroin) and preparations.

8. Benzylmorphine and its salts (hydrochloride: peronine) and preparations.

9. Benzoylmorphine and its salts and preparations.

10. All other ethers and esters of morphine not included in Group B, and their salts and preparations.

11. Dihydromorphine, its salts (hydrochloride: paramorfan), and esters and their salts and preparations.

12. 6-methyldihydromorphine / Methyldihydromorphine / and its salts and preparations.

13. Dihydrodesoxymorphine (Desomorphine) and its salts and preparations.

14. 6-methyl- Δ^6 -desoxymorphine / Methyldesorphine / and its salts and preparations.

15. Morphine-N-oxide (genomorphine) and morphine-N-oxide compounds and other pentavalent nitrogen mor - phine compounds and their preparations.

16. Hydromorphone^{*} (dihydromorphinone) and its salts (hydrochloride: dilaudid) and esters and their salts and preparations.

17. Dihydrohydroxymorphinone / Oxymorphone / and its salts and preparations.

18. Dihydrooxydihydromorphinone and its salts and preparations.

19. Metopon*(7-methyldihydromorphinone) and its salts and preparations.

20. Hydrocodone* (dihydrocodeinone) and its salts and preparations (hydrochloride: dicodide).

21. Oxycodone* (dihydrohydroxycodeinone) and its salts (hydrochloride: eucodal), esters and preparations.

22. Acetyldihydrocodeinone or acetyldemethylodihydrothebaine / Thebacon/ and its salts (hydrochloride: acedicone), esters and preparations.

23. Cocaine and its salts and preparations; crude cocaine and its preparations. Exceptions: preparations containing not more than 0.03% cocaine, other than preparations for parenteral use and solutions and dilutions of cocaine in a solid or liquid inert substance.

24. Ecgonine and its derivatives and their addiction producing salts and preparations thereof.

Note concerning drugs in Group A

The drugs Nos. 1, 2, 3, 4 and 5 in the foregoing list do not come under the provisions of article 4, paragraph 4 of Act No. 1041 of 22 October 1954. The other drugs in this group are subject to the said provisions when used as such and in quantities exceeding 100 g.

GROUP B

1. Codeine (methylmorphine) and its salts and preparations.

2. Ethylmorphine (hydrochloride: dionine) and its salts and preparations.

3. Dihydrocodeine and its salts and preparations (Paracodine, Novicodine).

2) Note by the Secretariat: The words in square brackets have been inserted by the Secretariat. Proposed or recommended international non-proprietary names of drugs are underlined.

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4. Acetyldihydrocodeine (acetyldocone) and its salts and preparations.

5. Pholcodine* (morpholiny lethy Imorphine) and its salts and preparations.

6. Thebaine and its salts and preparations.

7. Myristyl ester of benzylmorphine / Myrophine / and its salts.

Exceptions:

(a) Preparations in the dry state (granulated, in tablets etc.) having a total content per gramme not exceeding 0.1 of drugs enumerated in Group B provided that the drugs are combined with other medicinal substances;

(b) Preparations in the form of solutions in non-inert liquids containing not more than 10% of the drugs enumerated in Group B, excluding those for hypodermic use in any form.

Note concerning drugs in Group B

The drugs in this group do not come under the provisions of article 14, paragraph 4, of Act No. 1041 of 22 October 1954.

GROUP C

1. Pethidine*: 1-methyl-4-phenylpiperidine-4-carboxylic acid ethyl ester and its salts and preparations: (Dolantin, Algil, Dolisina, Mephedine, Dolosil, Asmalina, Bellalgina, Simesalgina, etc.).

2. The isopropyl ester <u>/Properidine</u> and the other esters of 1-methyl-4-phenylpiperidine-4-carboxylic acid (Spasmodolisina, etc.).

3. 1-methyl-4-(3-hydroxyphenyl)-piperidine-4-carboxylic acid ethyl ester or 1-methyl-4-metahydroxyphenylpiperidine-4-carboxylic acid ethyl ester and its salts and preparations (Bemidone, Hydroxypethidine).

4. <u>Ketobemidone</u>*:4-(3-hydroxyphenyl)-1-methyl-4-piperidyl ethylketone or 1-methyl-4-metahydroxyphenyl-4-propionylpiperidine and its salts and preparations (Cliradon).

5. <u>Alphaprodine*: < -1, 3-dimethyl-4-phenyl-4-propionoxypiperidine and its salts and preparations (Nisentil).</u>

6. β -1,3-dimethyl-4-phenyl-4-propionoxypiperidine and its salts and preparations (Betaprodine, NU-1779).

7. <u>Betameprodine</u>* β -4-propionoxy-4-pheny1-1-methy1-3-ethylpiperidine β -1-methy1-3-ethy1-4-pheny1-4-propionoxypiperidine/ and its salts and preparations (NU-1932, meprodine).

8. <u>Methadone</u>: 4,4-diphenyl-6-dimethylamino-heptanone-3 or 6-dimethylamino-4,4-diphenyl-heptanone-3 and its salts and preparations (Polamidon C, Sedamidon, Dolamina, Levadone, Zefalgin, Mephenon, Ketalgin, Physeptone etc.).

9. Isomethadone*: 4,4-dipheny1-5-methy1-6-dimethylaminohexanone-3 or 6-dimethylamino-5-methy1-4,4dipheny1-3-hexanone and its salts and preparations.

10. 4,4-diphenyl-6-dimethylamino-3-hexanone or 6-dimethylamino-4,4-diphenyl-3-hexanone /Normethadone/ and its salts and preparations (Ticarda, Veryl).

11. 4,4-dipheny1-6-piperidino-3-heptanone / Dipipanone / and its salts and preparations (Piperidy1 amidone).

12. 4,4-diphenyl-6-dimethylaminoheptanol-3 or 6-dimethylamino-4,4-diphenyl-3-heptanol /Dimepheptanol/ and its salts and preparations (methadol, N.I.H.-2933).

13. 4-6-dimethylamino-4, 4-diphenyl-3-heptanol and its salts and preparations (Alphamethadol).

14. β -6-dimethylamino-4, 4-diphenyl-3-heptanol and its salts and preparations (Betamethadol).

15. 4,4-diphenyl-6-dimethylamino-3-acetoxyheptane or 6-dimethylamino-4,4-diphenyl-3-acetoxyheptane and its salts and preparations (Acetylmethadol, methadyl acetate, N.I.H. -2953).

16. & -6-dimethylamino-4, 4-diphenyl-3-acetoxyheptane (Alphacetylmethadol) and its salts and preparations.

17. 3-6-dimethylamino-4, 4-diphenyl-3-acetoxyheptane (Betacetylmethadol) and its salts and preparations.

18. <u>Phenadoxone</u>*: 4,4-diphenyl-6-morpholinoheptanone-3 or 6-morpholino-4,4-diphenyl-3-heptanone and its salts and preparations (Heptalgin etc.).

19. 4-morpholino-2, 2-diphenyl ethyl butyrate /Dioxaphetyl butyrate/ (Amidalgon).

20. Racemorphan⁴: DL-3-hydroxy-N-methylmorphinan and its salts and preparations.

21. Levorphanol*: L-3-hydroxy-N-methylmorphinan and its salts and preparations (Dromoran).

22. Racemethorphan*: DL-3-methoxy-N-methylmorphinan and its salts and preparations.

23. Levomethorphan^{*}: L-3-methoxy-N-methylmorphinan and its salts and preparations.

24. Dimethylthiambutene*: 3-dimethylamino-1,1-di-(2'-thienyl)-1-butene and its salts and preparations.

25. Ethylmethylthiambutene*: 3-ethylmethylamino-1,1-di-(2'-thienyl)-1-butene and its salts and preparations.

26. Diethylthiambutene⁺: 3-diethylamino-1, 1-di-(2'-thienyl)-1-butene and its salts and preparations.

27. 1,3-dimethyl-4-phenyl-4-propionoxyhexamethyleneimine /Proheptazine/ and its salts and preparations.

28. 3-hydroxy-N-phenethylmorphinan /Phenomorphan/ and its salts and preparations

29. 4-dimethylamino-1, 2-diphenyl-3-methyl-2-propionoxybutane / Propoxyphene/ and its salts and preparations.

Note concerning the drugs in Group C

The drugs in this group come under the provisions of article 14, paragraph 4, of Act No. 1041 of 22 October 1954 when used as such and in quantities exceeding 100 g.

DEFINITIONS

For the purposes of this list the generic term "opium" means raw opium, officinal opium and poppy capsules.

"Raw opium" means the coagulated juice obtained from the capsules of the Papaver somniferum L., which has been treated only to the extent necessary for packing and transport, whatever its content of morphine.

"Officinal opium" means opium which has undergone the processes necessary to adapt it for medical use in accordance with the requirements of the pharmacopoeia, whether in powder form or granulated or otherwise mixed with inert materials.

"Poppy capsules" means the fruit of all varieties of the Papaver somniferum L., under whatever name, and the fruit of other species of poppy which contain alkaloids liable to produce addiction.

"Coca leaves" means the leaf of Erythroxylum Coca Lamarck and the Erythroxylum novogranatense (Morris) Hieronymus and their varieties, belonging to the family of Erythroxylaceae and the leaf of other species of this genus from which it may be found possible to extract cocaine, either directly or by chemical transformation.

"Indian hemp" means the dried flowering or fruiting tops of the pistillate plant, Cannabis sativa L. from which the resin has not been extracted, under whatever name they may be designated in commerce.

"Mixed alkaloids of opium" is a mixture of the alkaloids contained in opium.

"Narcotic drug or preparation" means any drug which is enumerated in this list or which can be readily transformed into a "narcotic" drug. Chemical processes for obtaining the salts of a drug shall not be regarded as conversion but merely as operations for the formation of salts. The conversion of one drug into another shall be regarded as manufacture in relation to the drug produced.

Preparations

"Preparation" means the substance obtained by any treatment or processing of a drug enumerated herein in order to adapt it for medical use, and all officinal or non-officinal forms of such drugs or their principal active components, whether in solution or in combination with active or inert substances. The term does not include the extraction of alkaloids from raw materials or the conversion of alkaloids into other substances or their purification.

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The term also includes all galenical preparations, special medicinal preparations and all derivatives of the chemical compounds enumerated herein which possess similar properties or from which the original drug can be easily recovered.

Rome, 9 January 1957

TESSITORI, High Commissioner

* International non-proprietary name proposed or recommended by the World Health Organization.