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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

FEDERAL REPUBLIC OF GERMANY

Communicated by the Government of the Federal Republic of Germany

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 texts.

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E/NL.1963/80

Bundesgesetzblatt

30 April 1963, No. 22, pp. 209 and 210

THIRD ORDER CONCERNING SUBSTANCES PLACED ON THE SAME FOOTING AS NARCOTIC DRUGS

24 April 1963

Pursuant to section 1, paragraphs 2, 2a, 4, to section 4, paragraph 4, and to sections 7 and 12 of the Opium Act of 10 December 1929 (Reichsgesetzblatt I, p. 215), as amended by the Opium (Second Amendment) Act, dated 9 January 1934 (Reichsgesetzblatt I, p. 22), and having regard to article 129, paragraph 1, of the Basic Law, the Federal Government hereby orders as follows:

Section 1

The undermentioned substances shall be placed on the same footing as those mentioned in section 1, paragraph 1, sub-paragraph 1 (b), of the Opium Act:

Short name	Scientific designation
Methadone-intermediate	4-cyano-2-dimethylamino-4,4-diphenylbutane
Moramide-intermediate	2-methyl-3-morpholino-1,1-diphenylpropanecarboxylic acid
<u>Noracymethadol</u> ^{1/}	(⁺)-alpha-3-acetoxy-6-methylamino-4,4-diphenylheptane
Pethidine-intermediate-A	4-cyano-1-methyl-4-phenylpiperidine
Pethidine-intermediate-B (norpethidine)	4-phenylpiperidine-4-carboxylic acid ethyl ester
Pethidine-intermediate-C	1-methyl-4-phenylpiperidine-4-carboxylic acid

Section 2

The undermentioned substance and its salts shall be placed on the same footing as the substances mentioned in section 1, paragraph 1, sub-paragraph 2 of the Opium Act:

Shortname	Scientific designation
<u>Nicocodine</u>	6-nicotinylcodeine

Section 3

(1) A person who, on the date of the entry into force of this Order, is engaged in the manufacture or processing of one or more of the substances or salts mentioned in sections 1 or 2, may continue, pending a decision concerning his application for a licence under section 3, paragraph 1, of the Opium Act, to manufacture or process these substances to the same extent as before.

(2) If the application for the licence is not submitted within one month after the entry into force of this Order, the right to manufacture and process the said substances shall expire at the end of the month.

Section 4

(1) A person who, on the date of the entry into force of this Order, has in his possession one or more of the substances mentioned in Section 1, or preparations of these substances, or the substance mentioned in section 2 or one or more of its salts, shall be under a duty to report particulars of the nature and quantity of the substances and preparations in question to the Federal Department of Health (Federal Opium Office) within two weeks after the entry into force of this Order.

(2) A person who, on the date of the entry into force of this Order, has in his possession one or more of the substances mentioned in section 1, or preparations of these substances, or the substance mentioned in section 2 or one or more of its salts, and who does not wish to apply for a licence under section 3, paragraph 1, of the Opium Act, may, within two weeks after the entry into force of this Order, deliver or sell these substances

^{1/} Note by the Secretariat: Proposed or recommended international non-proprietary names of drugs are underlined.

or preparations without a supply coupon to an undertaking which is authorized to deal in narcotic drugs. The undertaking shall be under a duty to report the name of the former owner and particulars of the nature and quantity of the substances or preparations acquired to the Federal Department of Health (Federal Opium Office) within three months after the entry into force of this Order.

(3) With respect to persons who do not require a licence under section 3, paragraph 4, of the Opium Act, paragraphs (1) and (2) above shall apply only in so far as the substances mentioned in section 1, or preparations of these substances, are concerned.

Section 5

If the substance mentioned in section 2, or its salts, should be contained in packages which do not satisfy the requirements of the regulations issued pursuant to section 7 of the Opium Act concerning the advertisement and labelling of medicaments containing narcotic drugs, the said substance and its salts may still be supplied in these packages in the wholesale trade for three months, and in pharmacies for six months, after the entry into force of this order.

Section 6

The Federal Minister of Health is hereby empowered to publish a revised list, arranged in alphabetical order, of the substances and their salts placed on the same footing as the substances mentioned in section 1, paragraph 1, sub-paragraphs 1 (b) and 2 of the Opium Act.

Section 7

This Order shall also apply to the Land Berlin in so far as it is put into force in the said Land.

Section 8

This Order shall enter into force on 1 May 1963.

Bonn, 24 April 1963

LUDWIG ERHARD

for the Federal Chancellor

SCHWARZHAUPT

Federal Minister of Health

E/NL.1963/81

Bundesgesetzblatt
30 April 1963, No. 22, pp. 210 and 211

ORDER AMENDING THE ORDER CONCERNING THE
PRESCRIPTION OF MEDICAMENTS CONTAINING NARCOTIC DRUGS
AND THE DISPENSING OF SUCH MEDICAMENTS IN PHARMACIES^{*/}

24 April 1963

Pursuant to section 1, paragraphs 4 and 5, and to sections 8 and 12 of the Opium Act of 10 December 1929 (Reichsgesetzblatt I, p. 215), as amended by the Opium (Second Amendment) Act dated 9 January 1934 (Reichsgesetzblatt I, p. 22) and having regard to article 129, paragraph 1, of the Basic Law, the Federal Government hereby orders as follows:

Section 1

The Order of 19 December 1930 concerning the prescription of medicaments containing narcotic drugs and the dispensing of such medicaments in pharmacies (Reichsgesetzblatt I, p. 635), as most recently amended by the Order of 25 October 1961^{2/} amending the Order concerning the prescription of medicaments containing narcotic drugs and the dispensing of such medicaments in pharmacies (Bundesgesetzblatt I, p. 1915), is hereby amended in the following respects:

1. Section 7, paragraph 2, shall read:

"(2) It is unlawful to prescribe medicaments which contain the following substances or preparations:

1. Allylpröidine^{1/}
2. Benzethidine
3. Clonitazene
4. Diampromide
5. Ecgonine
6. Esters of morphine, except diacetylmorphine [heroin]^{3/} and nicomorphine (dinicotinic acid ester of morphine)
7. Etonitazene
8. Furethidine
9. Hydromorphinol
10. Coca leaves or preparations of coca leaves

^{*/} Amends Bundesgesetzblatt III, 2121-6-5.

^{2/} Note by the Secretariat: E/NL.1961/102.

^{3/} Note by the Secretariat: The words in square brackets have been inserted by the Secretariat.

11. Levophenacymorphan
 12. Metazocine
 13. Methadone-intermediate
 14. Moramide-intermediate
 15. Myrophine
 16. Noracymethadol
 17. Norlevorphanol
 18. Pethidine-intermediate-A
 19. Pethidine-intermediate-B
 20. Pethidine-intermediate-C
 21. Phenampromide
 22. Phenazocine
 23. Piminodine
2. In section 9, paragraph 1, "32. Levomethadone 0.1 g" shall be inserted after "31. Laudanum or a preparation similar to laudanum 0.4 g". Numbers 32 to 61 become numbers 33 to 62.
 3. In section 10, paragraph 1, "2. Levomethadone 0.25 g" shall be inserted after "1. Amphetamine 1.0 g". Numbers 2 to 6 become numbers 3 to 7.
 4. Section 10 a, paragraph 1, shall read:
"(1) In prescribing medicaments which contain
 1. Acetyldihydrocodeine
 2. Ethylmorphine
 3. Benzylmorphine
 4. Dihydrocodeine
 5. Codeine
 6. Niccocodine or
 7. Pholcodineor their salts, and which are to be dispensed, under one prescription, on more than one occasion, the medical practitioner, dentist or veterinary surgeon shall specify how often and until what date they may be dispensed."
 5. Section 19, paragraph 4, sub-paragraph 3, shall read:
"3. instructions for use, which must show the individual dose and how frequently it is to be administered; in the case of the medicaments referred to in section 10 a,

paragraphs 1, 2, 3 and 5, these instructions for use may be omitted, if such instructions are given on the outer wrapping, on the container or on a slip enclosed with the package."

6. In section 26, the fourth sentence shall read:

"The prescriptions shall be retained in the pharmacies, with the exception of the prescriptions which are returnable by the pharmacy concerned to the social insurance bodies, including the sickness insurance funds (Ersatzkassen), and of the prescriptions which are chargeable to the bodies responsible for the cost of benefits pursuant to the Federal Assistance Act or to the enactments declaring the said Act to be applicable, and the prescriptions which are chargeable to the Federal Armed Forces (Bundeswehr), to the civilian alternative service (ziviler Ersatzdienst), to the State police administrations or to the associations for public or communal welfare."

Section 2

The Federal Minister of Health is hereby empowered to publish the revised text of the Order concerning the prescription of medicaments containing narcotic drugs and the dispensing of such medicaments in pharmacies.

Section 3

This Order shall apply to the Land Berlin in so far as it is put into force in the said Land.

Section 4

This Order shall enter into force on 1 May 1963.

Bonn, 24 April 1963

LUDWIG ERHARD

for the Federal Chancellor

SCHWARZHAUPT

Federal Minister of Health

E/NL.1963/82

Bundesgesetzblatt
30 April 1963, No. 22, p. 212

ORDER CONCERNING THE WAIVER OF COMPULSORY SUPPLY COUPONS FOR NARCOTIC DRUGS**/

24 April 1963

Pursuant to section 1, paragraph 4, section 4, paragraph 4, and section 12 of the Opium Act of 10 December 1929 (Reichsgesetzblatt I, p. 215), as amended by the Opium (Second Amendment) Act dated 9 January 1934 (Reichsgesetzblatt I, p. 22), and having regard to article 129, paragraph 1, of the Basic Law, the Federal Government hereby orders as follows:

**/ Repeals Bundesgesetzblatt III 2121-6-9.

Section 1

Supply coupons, as required under section 4, paragraph 1, of the Opium Act, shall not be necessary in respect of:

1. the substances mentioned in section 1, paragraph 1, sub-paragraph 2, of the Opium Act and substances placed on the same footing as the aforesaid substances, and their salts;
2. the following substances and preparations:
 - (a) Preparations containing benzylmorphine or preparations of the salts of benzylmorphine,
 - (b) Cardiazol-dicodid drops containing 0.005 g of dicodid /hydrocodone/ ^{1/3/} hydrochloride and 0.1 g of cardiazol in 1 g solution,
 - (c) Preparations containing diphenoxylate in tablet form, which do not contain more than 2.5 mg of diphenoxylate per tablet and which in addition contain at least 0.025 mg of atropine sulphate,
 - (d) Extract of cannabis indica,
 - (e) Herba cannabis indicae,
 - (f) Neurophilin pills for medicinal purposes containing 0.05 g of opium, 0.02 g of radix valerianae, 0.005 g of extractum aloes and 0.002 g of endophenolphthalein,
 - (g) Pulvis ipecacuanhae opiatus, including tablets,
 - (h) Tincture of cannabis indica.

Section 2

(1) A person holding a licence under section 3, paragraph 1, of the Opium Act who sells or dispenses any of the substances or preparations mentioned in section 1 shall report to the Federal Department of Health (Federal Opium Office) within the first month of every quarter of the calendar year particulars of the total quantities sold or dispensed during the preceding quarter and of the persons to whom these quantities were supplied. If no substances or preparations have been sold or dispensed, this shall be reported. The recipients, in so far as they hold trading licences under section 3, paragraph 1, of the Opium Act, shall report to the Federal Department of Health (Federal Opium Office) within the first month of each quarter of the calendar year particulars of the total quantities of such substances and preparations which they received during the preceding quarter and of the stock remaining in their possession at the end of the quarter.

(2) If any of the substances or preparations mentioned in section 1 are sold or delivered to pharmacies, only the total quantities involved shall be reported.

Section 3

This Order shall also apply to the Land Berlin, in so far as it is put into force in the said Land.

Section 4

This Order shall enter into force on 1 May 1963. Simultaneously the Order of 26 September 1960⁴/ concerning the waiver of compulsory supply coupons for narcotic drugs (Bundesgesetzblatt I, p.773) shall cease to have effect.

Bonn, 24 April 1963

LUDWIG ERHARD

for the Federal Chancellor

SCHWARZHAUPT

Federal Minister of Health

Bundesgesetzblatt

30 April 1963, No. 22, p.213

E/NL.1963/83

PUBLICATION OF THE REVISED LIST OF
SUBSTANCES PLACED ON THE SAME FOOTING AS THE
SUBSTANCES MENTIONED IN SECTION 1, PARAGRAPH 1,
SUB-PARAGRAPHS 1 (b) and 2, OF THE OPIUM ACT ***/

24 April 1963

Pursuant to section 6 of the Third Order concerning substances placed on the same footing as narcotic drugs dated 24 April 1963⁵/ (Bundesgesetzblatt I, p. 209), the list of substances placed on the same footing as the substances mentioned in section 1, paragraph 1, sub-paragraphs 1 (b) and 2, of the Opium Act of 10 December 1929 (Reichsgesetzblatt I, p. 215), as amended by the Opium (Second Amendment) Act, dated 9 January 1934 (Reichsgesetzblatt I, p. 22), is hereby published as revised by the aforesaid Order, by the Order concerning substances placed on the same footing as narcotic drugs dated 26 September 1960⁶/ (Bundesgesetzblatt I, p. 765) and by the Second Order concerning substances placed on the same footing as narcotic drugs dated 25 October 1961⁷/ (Bundesgesetzblatt I, p. 1909).

Bonn, 24 April 1963

SCHWARZHAUPT

Federal Minister of Health

4/ Note by the Secretariat: E/NL. 1960/125.

***/ Concerns Bundesgesetzblatt III, 2121-6-8 as published on 26 October 1961 (Bundesgesetzblatt I, p. 1911).

5/ Note by the Secretariat: E/NL. 1963/80.

6/ Note by the Secretariat: E/NL. 1960/122.

7/ Note by the Secretariat: E/NL. 1961/101.

List of substances placed on the same footing as the substances mentioned in section 1, paragraph 1, sub-paragraphs 1 (b) and 2 of the Opium Act

I.

The undermentioned substances are placed on the same footing as the substances mentioned in section 1, paragraph 1, sub-paragraph 1 (b) of the Opium Act:

Short name	Scientific designation
1. <u>Acetylmethadol</u> ^{1/}	3-acetoxy-6-dimethylamino-4,4-diphenylheptane
2. <u>Ethylmethylthiambutene</u>	3-ethylmethylamino-1,1-di-(2'-thienyl)-1-butene
3. <u>Allylprodine</u>	3-allyl-1-methyl-4-phenyl-4-propionoxypiperidine
4. <u>Alphacetylmethadol</u>	alpha-3-acetoxy-6-dimethylamino-4,4-diphenylheptane
5. <u>Alphameprodine</u>	alpha-3-ethyl-1-methyl-4-phenyl-4-propionoxypiperidine
6. <u>Alphamethadol</u>	alpha-6-dimethylamino-4,4-diphenyl-3-heptanol
7. <u>Alphaprodine</u>	alpha-1,3-dimethyl-4-phenyl-4-propionoxypiperidine
8. <u>Amphetamine</u>	1-phenyl-2-aminopropane
9. <u>Anileridine</u>	1- <u>para</u> -aminophenethyl-4-phenylpiperidine-4-carboxylic acid ethyl ester
10. <u>Benzethidine</u>	1-(2-benzoyloxyethyl)-4-phenylpiperidine-4-carboxylic acid ethyl ester
11. <u>Betacetylmethadol</u>	beta-3-acetoxy-6-dimethylamino-4,4-diphenylheptane
12. <u>Betameprodine</u>	beta-3-ethyl-1-methyl-4-phenyl-4-propionoxypiperidine
13. <u>Betamethadol</u>	beta-6-dimethylamino-4,4-diphenyl-3-heptanol
14. <u>Betaprodine</u>	beta-1,3-dimethyl-4-phenyl-4-propionoxypiperidine
15. <u>Clonitazene</u>	(2- <u>para</u> -chlorobenzyl)-1-diethylaminoethyl-5-nitrobenzimidazole
16. <u>Desomorphine</u>	dihydrodeoxymorphine
17. <u>Diampromide</u>	N-(2-(N-methylphenethylamino) propyl)-propionanilide
18. <u>Diethylthiambutene</u>	3-diethylamino-1,1-di-(2'-thienyl)-1-butene
19. <u>Dimenoxadol</u>	2-dimethylaminoethyl-1-ethoxy-1,1-diphenylacetate
20. <u>Dimepheptanol</u>	6-dimethylamino-4,4-diphenyl-3-heptanol
21. <u>Dimethylthiambutene</u>	3-dimethylamino-1,1-di-(2'-thienyl)-1-butene
22. <u>Dioxaphetyl butyrate</u>	ethyl-4-morpholino-2,2-diphenylbutyrate
23. <u>Diphenoxylate</u>	1-(3-cyano-3,3-diphenylpropyl)-4-phenylpiperidine-4-carboxylic acid ethyl ester
24. <u>Dipipanone</u>	4,4-diphenyl-6-piperidino-3-heptanone
25. D-Moramide [<u>dextromeramide</u>] ^{3/}	(+)-4-(2-methyl-4-oxo-3,3-diphenyl-4-(1-pyrrolidinyl) butyl) morpholine

26. <u>Etonitazene</u>	1-diethylaminoethyl-2- <u>para</u> -ethoxybenzyl-5-nitrobenzimidazole
27. <u>Etozeridine</u>	1-(2-(2-hydroxyethoxy)-ethyl)-4-phenylpiperidine-4-carboxylic acid ethyl ester
28. <u>Furethidine</u>	1-(2-tetrahydrofurfuryloxyethyl)-4-phenylpiperidine-4-carboxylic acid ethyl ester
29. <u>Hydromorphenol</u>	14-hydroxydihydromorphine
30. <u>Hydroxypethidine</u>	4- <u>meta</u> -hydroxyphenyl-1-methylpiperidine-4-carboxylic acid ethyl ester
31. <u>Isomethadone</u>	6-dimethylamino-5-methyl-4,4-diphenyl-3-hexanone
32. <u>Ketobemidone</u>	4- <u>meta</u> -hydroxyphenyl-1-methyl-4-propionylpiperidine
33. <u>Levomethorphan</u>	(-)-3-methoxy-N-methylmorphinan
34. <u>Levomoramide</u>	(-)-4-(2-methyl-4-oxo-3,3-diphenyl-4-(1-pyrrolidinyl)butyl) morpholine
35. <u>Levophenacymorphan</u>	(-)-3-hydroxy-N-phenacymorphinan
36. <u>Levorphanol</u>	(-)-3-hydroxy-N-methylmorphinan
37. <u>Metazocine</u>	2'-hydroxy-2,5,9-trimethyl-6,7-benzomorphan
38. <u>Methadone</u>	6-dimethylamino-4,4-diphenyl-3-heptanone
39. Methadone-intermediate	4-cyano-2-dimethylamino-4,4-diphenylbutane
40. Methylamphetamine	1-phenyl-2-methylaminopropane
41. <u>Methyldesorphine</u>	6-methyl-delta-6-deoxymorphine
42. <u>Methyldihydromorphine</u>	6-methyldihydromorphine
43. Methylphenylpiperidine carboxylic acid esters, (including <u>pethidine</u> and <u>properidine</u>)	Esters of 1-methyl-4-phenylpiperidine-4-carboxylic acid
44. <u>Metopon</u>	5-methyldihydromorphinone
45. Moramide-intermediate	2-methyl-3-morpholino-1,1-diphenylpropanecarboxylic acid
46. <u>Morpheridine</u>	1-(2-morpholinoethyl)-4-phenylpiperidine-4-carboxylic acid ethyl ester
47. <u>Myrophine</u>	myristylbenzylmorphine
48. <u>Noracymethadol</u>	(⁺)-alpha-3-acetoxy-6-methylamino-4,4-diphenylheptane
49. <u>Norlevorphanol</u>	(-)-3-hydroxymorphinan
50. <u>Normethadone</u>	6-dimethylamino-4,4-diphenyl-3-hexanone
51. <u>Normorphine</u>	demethylmorphine
52. <u>Oxymorphone</u>	14-hydroxydihydromorphinone
53. <u>Pethidine</u>	1-methyl-4-phenylpiperidine-4-carboxylic acid ethyl ester
54. Pethidine-intermediate-A	4-cyano-1-methyl-4-phenylpiperidine
55. Pethidine-intermediate-B (norpethidine)	4-phenylpiperidine-4-carboxylic acid ethyl ester

56.	<u>Pethidine-intermediate-C</u>	1-methyl-4-phenylpiperidine-4-carboxylic acid
57.	<u>Phenadoxone</u>	6-morpholine-4,4-diphenyl-3-heptanone
58.	<u>Phenampromide</u>	N-(1-methyl-2-piperidinoethyl) propionanilide
59.	<u>Phenazocine</u>	2'-hydroxy-5,9-dimethyl-2-phenethyl-6,7-benzomorphan
60.	<u>Phenomorphin</u>	3-hydroxy-N-phenethylmorphinan
61.	<u>Phenoperidine</u>	1-(3-hydroxy-3-phenylpropyl)-4-phenylpiperidine-4-carboxylic acid ethyl ester
62.	<u>Piminodine</u>	4-phenyl-1-(3-phenylaminopropyl) piperidine-4-carboxylic acid ethyl ester
63.	<u>Proheptazine</u>	1,3-dimethyl-4-phenyl-4-propionoxyazacycloheptane
64.	<u>Properidine</u>	1-methyl-4-phenylpiperidine-4-carboxylic acid isopropyl ester
65.	<u>Racemethorphan</u>	(±)-3-methoxy-N-methylmorphinan
66.	<u>Racemoramide</u>	(±)-4-(2-methyl-4-oxo-3,3-diphenyl-4-(1-pyrrolidinyl) butyl) morpholine
67.	<u>Racemorphan</u>	(±)-3-hydroxy-N-methylmorphinan
68.	<u>Trimeperidine</u>	1,2,5-trimethyl-4-phenyl-4-propionoxypiperidine

II.

The undermentioned substances and their salts are placed on the same footing as the substances mentioned in section 1, paragraph 1, sub-paragraph 2, of the Opium Act:

Short name	Scientific designation
1. <u>Acetyldihydrocodeine</u>	acetyldihydrocodeine
2. <u>Dihydrocodeine</u>	dihydrocodeine
3. <u>Nicocodine</u>	6-nicotinylcodeine
4. <u>Pholcodine</u>	morpholinylethylmorphine

Bundesgesetzblatt
30 April 1963, No. 22, p.216

E/NL.1963/84

PUBLICATION OF THE AMENDED TEXT OF THE ORDER CONCERNING THE PRESCRIPTION OF MEDICAMENTS CONTAINING NARCOTIC DRUGS AND THE DISPENSING OF SUCH MEDICAMENTS IN PHARMACIES ****/

24 April 1963

Pursuant to section 2 of the Order of 24 April 1963^{8/} amending the Order concerning the prescription of medicaments containing narcotic drugs and the dispensing of such medicaments in pharmacies (Bundesgesetzblatt I, p.210), the text now in force of the Order of 19 December 1930 concerning the prescription of medicaments containing narcotic drugs and the dispensing of such medicaments in pharmacies (Reichsgesetzblatt I, p.635) is published below as amended by the aforesaid amending Order and by the amending Orders dated

****/ Replaces Bundesgesetzblatt III, 2121-6-5.

8/ Note by the Secretariat: E/NL.1963/81.

24 March 1931 (Reichsgesetzblatt I, p. 76),
8 July 1932 (Reichsgesetzblatt I, p. 349),
20 May 1933 (Reichsgesetzblatt I, p. 287),
12 June 1941 (Reichsgesetzblatt I, p. 328, 454),
31 July 1943 (Reichsgesetzblatt I, p. 453),
16 June 1953 (Bundesgesetzblatt I, p. 402), ^{9/}
26 September 1960 (Bundesgesetzblatt I, p. 769), ^{10/} and
25 October 1961 (Bundesgesetzblatt I, p. 1915). ^{2/}

These legislative provisions were enacted pursuant to section 1, paragraphs 4 and 5, and sections 8 and 12 of the Opium Act of 10 December 1929 (Reichsgesetzblatt I, p.215).

Bonn, 24 April 1963

SCHWARZHAUPT

Federal Minister of Health

ORDER
CONCERNING THE PRESCRIPTION OF MEDICAMENTS
CONTAINING NARCOTIC DRUGS AND THE DISPENSING
OF SUCH MEDICAMENTS IN PHARMACIES

as amended on 24 April 1963

I.

Scope of application of the Order

Section 1

(1) Prescriptions which are required for the purpose of obtaining medicaments containing narcotic drugs from public pharmacies may only be made out in the manner specified in the provisions of Part II of this Order.

(2) Medicaments containing narcotic drugs may not be supplied by public pharmacies, officially approved house dispensaries of medical practitioners or veterinary surgeons or by veterinary surgeons holding a licence under section 3 of the Opium Act except in conformity with the provisions of Part III of this Order.

(3) Particulars of the dispensing of medicaments containing narcotic drugs shall be entered in a book in the manner specified in the provisions of Part IV of this Order.

Section 2

The provisions of this Order shall apply also to medicaments containing not more than 0.2 per cent morphine or 0.1 per cent cocaine.

Section 3

The provisions of this Order shall also apply to the salts of the narcotic drugs which are referred to in the Order as bases. The quantity specified in respect of a base shall also apply to its salts.

9/ Note by the Secretariat: E/NL.1953/104.

10/ Note by the Secretariat: E/NL.1960/123.

Section 4

The provisions of this Order shall apply likewise in cases where a narcotic drug is placed on the market under a name different from that given in this Order.

Section 5

The provisions of this Order shall not apply to the prescription and dispensing of medicaments containing Indian hemp /cannabis/3/, extract of Indian hemp, tincture of Indian hemp or ripe or unripe opium poppy capsules.

II.

The prescription of medicaments containing narcotic drugs

A.

General provisions

Section 6

The said medicaments may be prescribed only by medical practitioners, dentists or veterinary surgeons and only if there are medical, dental or veterinary reasons for the use of the narcotic drug in question.

Section 7

(1) Medicaments containing more than one narcotic drug may not be prescribed. The foregoing provision does not apply to medicaments which contain substances mentioned in section 10 a, paragraph 1, by themselves or in combination with a substance or preparation mentioned in section 9, paragraph 1, or section 10, paragraph 1.

(2) It is unlawful to prescribe medicaments which contain the following substances or preparations:

1. Allylprodine 1/
2. Benzethidine
3. Clonitazene
4. Diampromide
5. Ecgonine
6. Esters of morphine, except diacetylmorphine and nicomorphine
(dinicotinic acid ester of morphine)
7. Etonitazene
8. Furethidine
9. Hydromorphenol
10. Coca leaves or preparations of coca leaves
11. Levophenacylmorphane
12. Metazocine
13. Methadone - intermediate
14. Moramide - intermediate
15. Myrophine
16. Noracymethadol

17. Norlevorphanol
18. Pethidine - intermediate - A
19. Pethidine - intermediate - B
20. Pethidine - intermediate - C
21. Phenampromide
22. Phenazocine
23. Piminodine

(3) Medicaments which contain phenoperidine may be prescribed only for the purpose of anaesthesia and only for general use in the hospitals and university clinics mentioned in section 9, paragraph 4, and in institutions placed on the same footing as university clinics. The purpose for which the drug is to be used shall be specified in the prescription.

B.

The prescribing of medicaments containing narcotic
drugs other than cocaine

Section 8

(1) It is unlawful to prescribe in their pure state the substances mentioned in section 1, paragraph 1, sub-paragraph 1 (a) to (c) of the Opium Act, or substances placed on the same footing as these substances, as well as narcophin, laudanon, pantopon or preparations similar to laudanon or pantopon. Section 7, paragraph 2, shall not be affected by this provision.

(2) It is unlawful to prescribe medicaments containing more than 15 per cent of morphine or diacetylmorphine (heroin). It is likewise unlawful to prescribe medicaments which in tablet form contain more than 30 per cent, and in other medicinal forms more than 15 per cent, of dihydrocodeinone (dicodid) /hydrocodone/, dihydromorphinone (dilaudid), /hydromerphone/, dihydrooxycodone (eucodal) /oxycodone/, dihydromorphine (paramorfan) acetyl - demethylo - dihydro - thebaine (acedicone) /thebacon/, morphine aminoxide (morphine-N-oxide, genomorphine), narcophin, laudanon, or pantopon, or a preparation similar to laudanon or pantopon.

Section 9

(1) The medicaments prescribed by the medical practitioner or dentist for a particular patient on any one day must not, in the aggregate, contain a quantity exceeding that specified below as the maximum dose of one of the undermentioned substances or preparations:

1. <u>Acetylmethadol</u>	0.2 g
2. <u>Ethylmethylthiambutene</u>	0.2 g
3. <u>Alphacetylmethadol</u>	0.2 g
4. <u>Alphameprodine</u>	0.2 g
5. <u>Alphamethadol</u>	0.2 g
6. <u>Alphaprodine</u>	0.2 g
7. Amphetamine	0.2 g
8. Amphetamine for use in the eye	0.5 g

9.	<u>Anileridine</u>	0.2 g
10.	<u>Betacetylmethadol</u>	0.2 g
11.	<u>Betameprodine</u>	0.2 g
12.	<u>Betamethadol</u>	0.2 g
13.	<u>Betaprodine</u>	0.2 g
14.	<u>Desomorphine</u>	0.03 g
15.	Diacetylmorphine [<u>heroin</u>] ^{2/}	0.03 g
16.	<u>Diethylthiambutene</u>	0.2 g
17.	Dihydromorphine	0.2 g
18.	<u>Dimenoxadol</u>	0.2 g
19.	<u>Dimepheptanol</u>	0.2 g
20.	<u>Dimethylthiambutene</u>	0.2 g
21.	<u>Dioxaphetyl butyrate</u>	0.2 g
22.	<u>Diphenoxylate</u>	0.05 g
23.	<u>Dipipanone</u>	0.2 g
24.	D-Moramide [<u>dextromoramide</u>]	0.1 g
25.	<u>Etoperidine</u>	0.2 g
26.	<u>Hydrocodone</u>	0.2 g
27.	<u>Hydromorphone</u>	0.03 g
28.	<u>Hydroxypethidine</u>	0.2 g
29.	<u>Isomethadone</u>	0.2 g
30.	<u>Ketobemidone</u>	0.2 g
31.	Laudanum or a preparation similar to laudanum	0.4 g
32.	Levomethadone	0.1 g
33.	<u>Levomethorphan</u>	0.03 g
34.	<u>Levomoramide</u>	0.2 g
35.	<u>Levorphanol</u>	0.03 g
36.	<u>Methadone</u>	0.2 g
37.	Methylamphetamine	0.1 g
38.	<u>Methyldesorphine</u>	0.2 g
39.	<u>Methyldihydromorphine</u>	0.2 g
40.	Methylphenylpiperidine carboxylic acid esters [<u>esters of 1-methyl-4- phenylpiperidine-4-carboxylic acid</u>] other than <u>pethidine</u>	0.2 g
41.	<u>Metopon</u>	0.03 g
42.	<u>Morpheridine</u>	0.2 g
43.	Morphine	0.2 g

44.	Morphine aminoxide (morphine-N-oxide, genomorphine)	0.2 g
45.	Narcophine	0.4 g
46.	<u>Nicomorphine</u>	0.2 g
47.	<u>Normethadone</u>	0.2 g
48.	<u>Normorphine</u>	0.2 g
49.	Opium or the corresponding quantity of an opium preparation	2.0 g
50.	<u>Oxycodone</u>	0.2 g
51.	<u>Oxymorphone</u>	0.03 g
52.	Pantopon or a preparation similar to pantopon	0.4 g
53.	<u>Pethidine</u>	1.0 g
54.	<u>Phenadoxone</u>	0.2 g
55.	<u>Phenomorphan</u>	0.2 g
56.	<u>Proheptazine</u>	0.2 g
57.	<u>Properidine</u>	0.2 g
58.	<u>Racemethorphan</u>	0.03 g
59.	<u>Racemoramide</u>	0.2 g
60.	<u>Racemorphan</u>	0.03 g
61.	<u>Thebacon</u>	0.2 g
62.	<u>Trimeperidine</u>	0.2 g

(2) In special cases, the medical practitioner may prescribe for a particular patient on any one day medicaments which contain

more than 2 g of opium or the corresponding quantity
of an opium preparation, or

more than 0.2 g of morphine;

in such cases he shall note in a special book (Morphine Book), with pages numbered consecutively, particulars of the case which shall show clearly the patient's name, address and age, and the nature of the disease as diagnosed by the medical practitioner which requires that the quantity specified in paragraph 1. for morphine or opium should be exceeded. After these particulars, the medical practitioner shall in each case enter the date of the prescription, the quantity of morphine, opium or opium preparation contained in the medicament, and the period for which the medicament is prescribed. If the medicament is intended for a drug addict, the medical practitioner shall in addition enter in the Morphine Book the answers to the following questions:

What is the nature of the drug addiction?

For how long has the patient been an addict?

Has any withdrawal treatment been given?

If so, when, in which institution, or under which medical practitioner and with what success?

What quantity of the drug is allegedly required daily?

What quantity of the drug is considered necessary for medical reasons at the time when these particulars are being noted?

Why is no withdrawal treatment being applied at the present time?

When will such treatment begin?

On the prescription (section 19), the medical practitioner shall, in the cases referred to in this paragraph, add before his signature the words "Registered prescription" in his own handwriting.

(3) The medicaments prescribed by a medical practitioner on any one day for the purposes of his practice must not, in the aggregate, contain a quantity exceeding that specified in paragraph 1 as the maximum dose of one of the substances or preparations mentioned in that paragraph.

(4) Apart from cases where they may be prescribed for the treatment of a patient (paragraphs 1 and 2) and for the purposes of the practice (paragraph 3), medicaments containing the narcotic drugs mentioned in section 8, paragraph 1, may also be prescribed for the general requirements of public and non-profit hospitals, university clinics and institutions placed on the same footing as university clinics, as well as for the requirements of officially approved house dispensaries of medical practitioners and for the fitting-out of merchant ships. Paragraphs 1 to 3 shall not apply to such prescriptions.

Section 10

(1) The medicaments prescribed by the veterinary surgeon on any one day for an animal must not, in the aggregate, contain a quantity exceeding that specified in section 9, paragraph 1, as the maximum dose of one of the substances or preparations mentioned in that provision. Nevertheless, in respect of the under-mentioned substances or preparations, the maximum dose shall be that specified below:

1. Amphetamine	1.0 g
2. Levomethadone	0.25 g
3. <u>Methadone</u>	0.5 g
4. Morphine	0.5 g
5. Opium or the corresponding quantity of an opium preparation	15.0 g
6. <u>Oxycodone</u>	0.3 g
7. <u>Pethidine</u>	2.0 g

(2) In special cases, the veterinary surgeon may prescribe for a particular animal on any one day medicaments which contain

more than 15 g of opium or the corresponding quantity of an opium preparation, or
more than 0.5 g of morphine;

in such cases he shall note in a special book (Morphine Book), with pages numbered consecutively, particulars of the case which shall show clearly what kind of animal is involved, the name and address of the person in charge of the animal, the disease which makes it necessary to exceed the quantity specified in paragraph 1 for morphine or opium, the date of the prescription and the quantity of morphine, opium or opium preparation contained in the medicament. In such cases, the veterinary surgeon shall add on the prescription (section 19) before his signature the words "Registered prescription" in his own handwriting.

(3) The medicaments prescribed by the veterinary surgeon on any one day for the purposes of his practice must not, in the aggregate, contain a quantity exceeding that specified in paragraph 1 as the maximum dose of one of the substances or preparations mentioned in that paragraph.

(4) Apart from the cases where they may be prescribed for the treatment of an animal (paragraphs 1 and 2) and for the purposes of his practice (paragraph 3), the veterinary surgeon may prescribe medicaments containing the narcotic drugs mentioned in section 8, paragraph 1, for the general requirements of university veterinary clinics and institutions placed on the same footing as such clinics, as well as for the requirements of officially approved house dispensaries of veterinary surgeons. Paragraphs 1 to 3 shall not apply to such prescriptions.

Section 10 a

(1) In prescribing medicaments which contain

1. Acetyldihydrocodeine
2. Ethylmorphine
3. Benzylmorphine
4. Dihydrocodeine
5. Codeine
6. Nicocodine
7. Pholcodine

or their salts, and which are to be dispensed, under one prescription, on more than one occasion, the medical practitioner, dentist or veterinary surgeon shall specify how often and until what date they may be dispensed.

(2) Medicaments which contain ethylmorphine or codeine together with other active ingredients may be dispensed repeatedly, even in the absence of the particulars required under paragraph 1, if the individual dose shown in the prescription does not contain more than 0.1 g of ethylmorphine or codeine.

(3) Medicaments which contain dihydrocodeine may be dispensed repeatedly even in the absence of the particulars required under paragraph 1, if the individual dose shown in the prescription does not contain more than 0.05 g of dihydrocodeine.

(4) Paragraph 1 shall also apply to the prescription of medicaments containing normethadone, on condition that:

1. if the medicaments are in the form of a solution, they must not contain more than 1 per cent of normethadone and they must, in addition, contain at least 2 per cent

of oxyphenylmethylaminopropanol, as well as at least 1 per cent of oxyethylated coco-nut oil alcohol EO 18 (ethylene oxide); or

2. if they are in tablet form, each tablet must not contain more than 7.5 mg of normethadone and must contain, in addition, at least 10 mg of oxyphenylmethylaminopropanol, as well as at least 6 mg of oxyethylated coco-nut oil alcohol EO 18 (ethylene oxide).

The medicament as prepared for dispensing must not contain a solution of more than 15 cc or consist of more than 20 tablets.

(5) The provisions of paragraph 1 also apply to the prescription of medicaments which contain diphenoxylate if the medicaments in question are in the form of tablets and each tablet contains not more than 2.5 mg of diphenoxylate and in addition at least 0.025 mg of atropine sulphate. Not more than 20 tablets shall be dispensed at any one time.

Section 11

The Morphine Book (section 9, paragraph 2, section 10, paragraph 2) shall be kept for at least five years after the date of the last entry and shall be produced to the competent medical officer or veterinary officer on demand.

C.

The prescription of medicaments containing cocaine

Section 12

Cocaine may not be prescribed in its pure state.

Section 13

(1) Medicaments containing cocaine which are intended for the personal use of a patient may be prescribed by the medical practitioner in the form of a solution or ointment only, and only if the intended purpose cannot be achieved in any other way. Subject to this condition, the medical practitioner may prescribe for application to the eye a solution or an ointment which does not contain more than 2 per cent of cocaine; for other purposes he may prescribe a solution containing not more than 1 per cent of cocaine and at the same time not less than 0.1 per cent of atropine sulphate.

(2) The quantity of cocaine prescribed by the medical practitioner for the personal use of a patient on any one day may not be more than 0.1 g.

(3) On each prescription (section 19) of a medicament containing cocaine which is intended for the personal use of a patient, the medical practitioner shall add, before his signature, the words "Registered prescription" in his own handwriting. If the medicament is intended for use in the eyes, this purpose shall be specified in the directions for use.

Section 14

(1) For the purposes of his practice, the medical practitioner or dentist, as the case may be, may not prescribe medicaments containing cocaine except for the treatment of the

eyes, larynx, nose and ears and for surgical treatment of the throat or jaw, and they may only prescribe these medicaments if the intended anaesthesia cannot be achieved in any other way and if the medicament in question is intended for direct application to the eye or to the mucous membranes of the said parts of the body. For these purposes, the medical practitioner may prescribe cocaine only in the form of a solution having a cocaine content not exceeding 20 per cent, or in the form of tablets for application to the eyes or of an ointment with a cocaine content not exceeding 2 per cent, and the dentist may prescribe it only in the form of a solution with a cocaine content not exceeding 20 per cent. On each prescription (section 19) for a medicament containing cocaine which is intended for the purpose of his practice, the medical practitioner or dentist shall add, before his signature, the words "Registered prescription" in his own handwriting.

(2) The quantity of cocaine prescribed by the physician or dentist for the purpose of his practice on any one day may not exceed 1 g.

Section 15

In respect of each prescription of a medicament containing cocaine, the medical practitioner or dentist shall enter particulars in a special book (Cocaine Book) with consecutively numbered pages. In the case of a prescription for a medicament intended for a patient's own use (section 13), the medical practitioner shall note in the book the patient's name, the disease diagnosed by the medical practitioner which necessitates the prescription of a medicament containing cocaine, the date of the prescription and the quantity of cocaine contained in the medicament. In the case of prescriptions for such medicaments intended for the purposes of his practice (section 14), the medical practitioner or dentist shall note the date of prescription and the quantity of cocaine contained in the medicament.

Section 16

Apart from the cases in which medicaments containing cocaine may be prescribed for the treatment of a patient (section 13) and for the purposes of the practice (section 14), such medicaments may also be prescribed for the general requirements of public and non-profit hospitals, university clinics and institutions placed on the same footing as such clinics and for the fitting-out of merchant ships. Sections 13 to 15 shall not apply to such prescriptions. Even in these cases, however, cocaine may be prescribed only in the form of a solution having a cocaine content not exceeding 20 per cent, or in the form of a tablet for application to the eyes or of an ointment with a cocaine content not exceeding 2 per cent.

Section 17

(1) For the purposes of his practice, the veterinary surgeon may not prescribe medicaments containing cocaine except for the treatment of the hoof and eye. For the purpose of such treatment cocaine may be prescribed only in the form of a solution having a cocaine content not exceeding 20 per cent, or in the form of a tablet for application to the eyes or of an ointment having a cocaine content of not more than 2 per cent. On each prescription (section 19) for a medicament containing cocaine which is intended for the purpose of his practice, the veterinary surgeon shall add, before his signature, the words "Registered prescription" in his own handwriting.

(2) In respect of each prescription of a medicament containing cocaine, the veterinary surgeon shall enter particulars in a special book (Cocaine Book) with consecutively numbered pages, which shall show the date of the prescription and the quantity of cocaine contained in the medicament.

(3) The quantity of cocaine prescribed by the veterinary surgeon on any one day for the purpose of his practice may not exceed 1 g.

(4) Apart from the cases in which medicaments containing cocaine may be prescribed for the purposes of his practice (paragraph 1), the veterinary surgeon may prescribe such medicaments for the general requirements of university veterinary clinics and institutions placed on the same footing as such clinics. Paragraphs 1 to 3 shall not apply to such prescription. Even in these cases, however, cocaine may be prescribed only in the form of a solution with a cocaine content not exceeding 20 per cent, or in the form of a tablet for application to the eyes or of an ointment with a cocaine content not exceeding 2 per cent.

Section 18

The Cocaine Book (section 15, section 17, paragraph 2) shall be kept for at least five years after the date of the last entry and shall be produced to the competent medical officer or veterinary officer on demand.

D.

Form and contents of the prescription

Section 19

(1) In addition to specifying the ingredients of the medicament in question and their quantities, prescriptions shall contain the following particulars:

- (a) the name of the medical practitioner, dentist or veterinary surgeon, his professional title and his address;
- (b) the date of the prescription;
- (c) directions for use clearly showing the individual dose and how often it is to be administered - in the case of prescriptions of medicaments containing cocaine or phenylaminopropane (Aktedron, Benzedrine, Elastonon) for application to the patient's eyes the purpose for which they are to be used shall also be specified;
- (d) the name and address of the patient for whom the medicament is intended; in the case of veterinary prescriptions, the kind of animal and the name and address of the person in charge of the animal;
- (e) the full signature, in his own hand, of the medical practitioner, dentist or veterinary surgeon;
- (f) in cases where this is required under section 9, paragraph 2, section 10, paragraph 2, section 13, paragraph 3, section 14, paragraph 1, and section 17, paragraph 1, the words "Registered prescription" in hand-writing before the signature.

(2) The particulars required under paragraph 1 shall be entered in ink or indelible pencil, but those required under sub-paragraph (a) need only be entered if they are not already printed or stamped on the prescription form.

(3) In the case of prescriptions for the general requirements of public and non-profit hospitals, university clinics and institutions placed on the same footing as such clinics,

for the purposes of the practice of the medical practitioner, dentist or veterinary surgeon, for the requirements of officially approved house dispensaries of medical practitioners and veterinary surgeons as well as for the fitting-out of merchant ships, the general purpose shall be stated instead of the particulars required under paragraph 1 (c) and (d).

(4) Paragraphs 1 to 3 shall not apply to prescriptions of medicaments which contain substances mentioned in section 10 a, paragraphs 1 to 3, or normethadone or diphenoxylate, in the form, composition and maximum doses specified in section 10 a, paragraphs 4 and 5. On such prescriptions the following particulars shall be given:

1. the name and address of the medical practitioner, dentist or veterinary surgeon;
2. the date of the prescription;
3. instructions for use, which must show the individual dose and how frequently it is to be administered; in the case of medicaments referred to in section 10 a, paragraphs 1, 2, 3 and 5, these instructions for use may be omitted, if such instructions are given on the outer wrapping, on the container or on a slip enclosed with the package;
4. the signature of the medical practitioner, dentist or veterinary surgeon.

If the medical practitioner, dentist or veterinary surgeon intends to administer the medicaments himself, he shall state on the prescription, instead of the instructions for use, "For use in practice" or "For use in hospital".

Section 20

Prescriptions may be neither post-dated nor pre-dated.

III.

The dispensing of medicaments containing narcotic drugs

A.

In public pharmacies

Section 21

(1) The said medicaments may not be dispensed in pharmacies except on production of a prescription made out by a medical practitioner, dentist or veterinary surgeon.

(2) Medicaments containing the narcotic drugs mentioned in section 8, paragraph 1, may be dispensed only

- against the prescription of a medical practitioner, intended for a particular patient, for the purposes of the practice of the prescribing medical practitioner, for the general requirements of public and non-profit hospitals, university clinics

and institutions placed on the same footing as such clinics, for the requirements of officially approved house dispensaries of medical practitioners or for the fitting-out of merchant ships;

- against the prescription of a dentist, intended for a particular patient, or for the general requirements of the university dental clinics and institutions placed on the same footing;
- against the prescription of a veterinary surgeon, intended for a particular animal, for the purposes of the practice of the prescribing veterinary surgeon, for the general requirements of university veterinary clinics and institutions placed on the same footing as such clinics, or for the requirements of an officially approved veterinary house dispensary.

(3) Medicaments containing cocaine may be dispensed only

- against the prescription of a medical practitioner, intended for a particular patient, for the purposes of the practice of the prescribing medical practitioner, for the general requirements of public and non-profit hospitals, university clinics and institutions placed on the same footing as such clinics or for the fitting-out of merchant ships;
- against the prescription of a dentist, intended for the purposes of the practice of the prescribing dentist, or for the general requirements of university dental clinics and institutions placed on the same footing;
- against the prescription of a veterinary surgeon, intended for the purposes of the practice of the prescribing veterinary surgeon or for the general requirements of the university veterinary clinics and institutions placed on the same footing.

(4) It is unlawful to dispense prescriptions which contravene the provisions of sections 7, 8 and 10 a, or which in the cases covered by section 9, paragraphs 1 and 3, and by section 10, paragraphs 1 and 3, are made out for quantities of narcotic drugs larger than those specified in those provisions. Prescriptions for medicaments containing cocaine may only be dispensed if,

with respect to the percentage of the cocaine content of the medicament,

with respect to the form of the medicament,

with respect to the quantity of cocaine contained in each medicament,

with respect to the admixture of atropine sulphate
in the case referred to in section 13, paragraph 1,

the medical practitioner, dentist or veterinary surgeon has made out the prescription in conformity with the provisions of sections 12, 13, 14, 16 and 17.

(5) Prescriptions may only be dispensed if they comply with the provisions of section 19. If, however, in the cases referred to in section 9, paragraph 1, or section 10, paragraph 1, the address of the patient or of the person in charge of the animal is not entered, the pharmacist shall not be under an obligation to refuse to dispense the prescription.

(6) A prescription made out by a medical practitioner for a medicament containing one of the narcotic drugs mentioned in section 8, paragraph 1, may be dispensed, even though it does not comply with the provisions of paragraphs 1 to 5, if the person carrying the prescription gives a credible assurance that an urgent emergency is involved which necessitates the immediate administration of the medicament. In such a case, the quantity of the narcotic drug supplied shall not exceed the quantity allowed under section 9, paragraph 1, in respect of the particular drug mentioned in the prescription. The particulars given by the person carrying the prescription shall be noted on the prescription. In addition, the quantity of the narcotic drug dispensed shall be noted.

(7) When dispensing medicaments which contain substances mentioned in section 10 a, paragraph 1, or normethadone or diphenoxylate, in the form, composition and maximum doses specified in section 10 a, paragraphs 4 and 5, the pharmacist shall note on the prescription the fact that the medicaments have been dispensed, as well as the date on which they were dispensed.

Section 22

- (1) The quantity mentioned in a prescription must be delivered in one lot.
- (2) Pre-dated prescriptions may not be dispensed.
- (3) Prescriptions for a patient in the case referred to in section 9, paragraph 2, may not be dispensed after the end of the fifth day following their issue.

Section 23

A pharmacy may not send medicaments outside its place of business unless it is one of the ten pharmacies nearest to the place of destination.

Section 24

If a medical practitioner, dentist or veterinary surgeon makes out a prescription which, under the foregoing provisions, may not be dispensed, the pharmacy shall note on the prescription, in ink or indelible pencil, the words "Dispensing of this prescription is unlawful". The name or style under which the pharmacy carries on business shall then be noted on the prescription, which shall be returned to the patient or bearer in a sealed envelope addressed to the medical practitioner, dentist or veterinary surgeon for transmittal to him, or else shall be delivered directly to the medical practitioner, dentist or veterinary surgeon in some other suitable way.

B.

In the officially approved house dispensaries of
medical practitioners and veterinary surgeons

Section 25

Medicaments may not be dispensed in the officially approved house dispensaries of medical practitioners and veterinary surgeons or by veterinary surgeons holding a licence under section 3 of the Opium Act unless the medical practitioner or veterinary surgeon concerned is authorized to prescribe the medicament under Part II of this Order. The prescription (section 19) shall be replaced by an entry in the Narcotics Book (section 29). The provisions concerning the Morphine Book (section 9, paragraph 2, section 10, paragraph 2) and the Cocaine Book (section 15, section 17, paragraph 2) shall apply, mutatis mutandis.

IV.

Proof of disposal of narcotic drugs

A.

In public pharmacies

Section 26

On prescriptions for medicaments prepared in a pharmacy, the date of preparation and the name of the person who prepared them shall be noted. On prescriptions for medicaments which were obtained from the trade in ready-made packages and which were dispensed in these packages, the date on which they were dispensed and the name of the person who dispensed them shall be noted. In addition, the name or style under which the pharmacy carries on business shall be noted on all prescriptions. The prescriptions shall be retained in the pharmacies, with the exception of the prescriptions which are returnable by the pharmacy concerned to the social insurance bodies including the sickness insurance funds (Ersatzkassen), and of the prescriptions which are chargeable to the bodies responsible for the cost of benefits, pursuant to the Federal Assistance Act or to the enactments declaring the said Act to be applicable, and the prescriptions which are chargeable to the Federal Armed Forces (Bundeswehr), to the civilian alternative service (ziviler Ersatzdienst), to the State police administrations or to the associations for public or communal welfare. The prescriptions so retained shall be numbered consecutively for each calendar year, in chronological order of the dispensing of the medicaments.

Section 27

(1) A register shall be kept of the medicaments dispensed. The Narcotics Books for Pharmacies (annexes I and II), which have consecutively numbered pages, shall be used for this purpose. The manager of the pharmacy, or his authorized deputy, shall each day register the medicaments dispensed by completing the appropriate columns in these books. Narcotics Book I shall be used for registering the dispensing of medicaments prepared in the pharmacy. Narcotics Book II shall be used for registering the dispensing of medicaments which were obtained from the trade in ready-made packages intended for the dispensing to the public and which were dispensed in these packages.

(2) Narcotic drugs and medicaments which are delivered by parent pharmacies to branch pharmacies shall likewise be registered in the Narcotics Books in the manner specified in paragraph 1.

(3) At the end of each calendar month, the quantities of the narcotic drugs registered during the month in each column of Narcotics Book I must be added up.

(4) At the end of each calendar month, the manager of the pharmacy shall enter a note in the Narcotics Book indicating that he has inspected it; in Narcotics Book I this note shall be entered below the entries required in paragraph 3 and in Narcotics Book II after the last entry.

Section 28

(1) The prescriptions, arranged in numerical order and filed according to calendar month, shall be kept for at least five years; the Narcotics Books shall likewise be kept for at least five years after the date of the last entry. The prescriptions, Narcotics Books or extracts from the latter shall be communicated on demand to the competent supervisory authority or to the Federal Ministry of Health (Federal Opium Office), or produced on the spot to the representatives of these authorities.

(2) While the Narcotics Books are in the possession of the authorities mentioned in paragraph 1, provisional records shall be kept, which shall be entered in the books upon their return.

B.

In the officially approved house dispensaries of medical practitioners and veterinary surgeons

Section 29

(1) In the officially approved house dispensaries of medical practitioners the Narcotics Book for House Dispensaries of Medical Practitioners (annex III), with consecutively numbered pages, shall be kept. Particulars of the dispensing of medicaments shall be entered in the appropriate columns of this book.

(2) In the officially approved house dispensaries of veterinary surgeons, and of veterinary surgeons holding a licence under section 3 of the Opium Act, the Narcotics Book for Veterinary Surgeons (annex IV), with consecutively numbered pages, shall be kept. Particulars of the use or dispensing of the medicaments shall be entered in the appropriate columns of this book, even if the medicaments or the narcotic drugs contained in the medicaments were obtained from a pharmacy against the prescription of a veterinary surgeon.

(3) The Narcotics Books shall be kept for at least five years after the date of the last entry. The Narcotics Books, or extracts from them, shall be communicated on demand to the competent supervisory authority or to the Federal Ministry of Health (Federal Opium Office), or produced on the spot to the representatives of these authorities.

(4) While the Narcotics Books are in the possession of the authorities mentioned in paragraph 3, provisional records shall be kept, which shall be entered in the books upon their return.

IV a.

Exceptions

Section 29 a

The provisions of sections 6 and 22 to 29 shall not apply to medicaments which contain substances mentioned in section 10 a, paragraph 1, or normethadone or diphenoxylate, in the form, composition and maximum doses specified in section 10 a, paragraphs 4 and 5.

Annex I

(to section 27, paragraph 1)

NARCOTICS BOOK I
for pharmacies

In the appropriate columns of this book particulars should be entered of the dispensing of medicaments containing narcotic drugs which were made up in the pharmacy. The quantity of the narcotic drug contained in the medicament should be entered in columns 8 to 28.

[illegible][illegible]

Annex II

(to section 27, paragraph 1)

NARCOTICS BOOK II
for pharmacies

In the appropriate columns of this book particulars should be entered of the dispensing of medicaments containing narcotic drugs which were obtained from the trade in ready-made packages intended for dispensing to the public and which were dispensed in these packages.

The name of the medicament and the size or contents of the package should be entered in columns 8 to 33; in the case of medicaments which are put on the market subdivided into units, the name of the medicament should be given, as well as the quantity of the narcotic drug contained in each unit and the number of units contained in the package.

Annex II: as revised by section 3 of the Order of 12 June 1941 (I.328), section 2, paragraph 4 of the Order of 16 June 1953 (I.402)^{7/} and section 2 of the Order of 26 September 1960 (I.769);^{8/} the columns left blank are to be used for entering particulars of narcotic drugs for which no columns are provided (section 2 of the Order of 26 September 1960, I.769).^{8/}

Serial No. on each page	Prescription No.	Date dispensed	Patient's name	Sickness insurance fund	Membership No. in sickness insurance fund (if stated in prescription)	Name of medical practitioner, dentist or, veterinary surgeon	Morphine	Laudanum	Narcophine	Pantopon	Dihydro-codeinone (Diacodid) <u>hydrocodone</u>	Dihydro-morphinone (Dilaudid) <u>hydromorphone</u>	Dihydrooxy-codeinone (Eucodal) <u>oxycodone</u>		
1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
1															
2															
3															

		Methyl-phenyl-piperidine carboxylic acid ethyl ester (Dolantine) <u>pethidine</u>	Phenyl-amino-propane (Actedron, Benzedrine, Elastonon), phenylmethyl-aminopropane (Pervitin)	Opium, extract of opium, tincture of opium (ordinary, containing saffron)													Serial No. on each page
17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33	34
																	1
																	2
																	3

Annex III
(to section 29,
paragraph 1)

NARCOTICS BOOK

for officially approved house dispensaries of medical practitioners

In the appropriate columns of this book particulars should be entered of the dispensing of medicaments containing narcotic drugs. If a medicament is dispensed which was made up in the medical practitioner's house dispensary, the quantity of the narcotic drugs contained in the medicament should be entered in columns 5 to 17. If a medicament which was obtained in a ready-made package intended for dispensing to the public is dispensed in the same package, the name of the medicament and the size or contents of the package should be entered in columns 18 to 38; in the case of medicaments which are put on the market subdivided into units, the name of the medicament should be given, as well as the quantity of the narcotic drug contained in each unit and the number of units contained in the package.

Annex III: as revised by section 3 of the Order of 12 June 1941 (I.328), section 2, paragraph 4 of the Order of 16 June 1953 (I.402)7/ and section 2 of the Order of 26 September 1960 (I.769)8/; the columns left blank are to be used for entering particulars of narcotic drugs for which no columns are provided (section 2 of the Order of 26 September 1960, I.769)8/.

Serial No. on each page	Date dispensed	Patient's name	Patient's address	Morphine	Diacetyl-morphine (heroin)	Opium	Tincture of opium (ordinary, containing saffron)	Laudanum	Narcophine	Pantopon							Morphine		
1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20
1 2 3																			
			Methyl-phenyl-piperidine carboxylic acid ethyl ester (Dolan-tine) (pathi-dine)	Phenyl-amino-propane (Actedron Bense-drine, Elasto-non), phenyl-methyl-amino-propane (Fervi-tin)	Opium, extract of opium, tincture of opium (ordinary, containing saffron)														Serial No. on each page
21	22	23	24	25	26	27	28	29	30	31	32	33	34	35	36	37	38		39 1 2 3

Annex IV

(to section 29, paragraph 2)

NARCOTICS BOOK

for officially approved house dispensaries of
veterinary surgeons and for veterinary surgeons
holding a licence under section 3 of the Opium Act

In the appropriate columns of this book particulars should be entered of the disposal and the dispensing of medicaments containing narcotic drugs. If a medicament made up in the veterinary surgeon's house dispensary is used or dispensed, the quantity of the narcotic drugs contained in the medicament should be entered in columns 6 to 15. If a medicament obtained in a ready-made package intended for dispensing to the public, is used or dispensed, the name of the medicament and the size or contents of the package should be entered in columns 16 to 36; in the case of medicaments which are put on the market subdivided into units, the quantity of the narcotic drug contained in each unit and the number of units contained in each package should be entered.

Annex IV: as revised by section 3 of the Order of 12 June 1941 (I.328), section 2, paragraph 4 of the Order of 16 June 1953 (I.402) and section 2 of the Order of 26 September 1960 (I.769); the columns left blank are to be used for entering particulars of narcotic drugs for which no columns are provided (section 2 of the Order of 26 September 1960, I.769).

Serial No. on each page	Date dis- pensed	Kind of Animal	Name of person in charge of animal	Address of that person	Morphine	Cocaine	Opium	Tincture of opium (ordinary, containing saffron)							Morphine		
1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18
1																	
2																	
3																	

			Methyl- phenyl- piperidine carboxylic acid ethyl ester (<u>Dolantine</u>) <u>/pethidine/</u>	Phenyl- amino- propane (Actedron, Benzedrine, Elastonon), phenyl- methyl- amino- propane (Pervitin)	Opium extract of opium, tincture of opium (ordinary, containing saffron)													Serial No. on each page
19	20	21	22	23	24	25	26	27	28	29	30	31	32	33	34	35	36	37
																		1
																		2
																		3