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E/NL.1961/101-103

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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.

INDEX

		Page
E/NL.1961/101	Second Order concerning substances placed on the same footing as narcotic drugs, 25 October 1961	1 - 3
E/NL.1961/102	Order amending the Order concerning the prescription of medicaments containing narcotic drugs and the dispensing of such medicaments in pharmacies, 25 October 1961	3 - 7
E/NL.1961/103	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, 26 October 1961	7 - 9

E/NL.1961/101

Bundesgesetzblatt
31 October 1961, No. 86, pp. 1909 and 1910

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

25 October 1961

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
<u>Clonitazene</u> ^{1/}	2- <u>para</u> -chlorobenzyl-1-diethylaminoethyl-5-nitrobenzimidazole
<u>Diampromide</u>	N-(2-(N-methylphenethylamino)propyl) propionanilide
<u>Diphenoxylate</u>	1-(3-cyano-3,3-diphenylpropyl)-4-phenylpiperidine-4-carboxylic acid ethyl ester
<u>Etonitazene</u>	1-diethylaminoethyl-2- <u>para</u> -ethoxybenzyl-5-nitrobenzimidazole
<u>Hydromorphenol</u>	14-hydroxydihydromorphine
<u>Phenampromide</u>	N-(1-methyl-2-piperidinoethyl) propionanilide
<u>Phenoperidine</u>	1-(3-hydroxy-3-phenylpropyl)-4-phenylpiperidine-4-carboxylic acid ethyl ester

Section 2

(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 mentioned in section 1 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 3

(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, 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, 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 or preparations without a supply coupon to an undertaking which is authorized to deal in narcotic drugs. The undertaking shall 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 a person who does not require a licence under section 3, paragraph 4, of the Opium Act, paragraphs 1 and 2 shall apply in so far only as the substances in question are clonitazene, diampromide, etonitazene, hydromorphenol, phenampromide or preparations of these substances.

^{1/}

Note by the Secretariat: Proposed or recommended international non-proprietary names of drugs are underlined.

Section 4

If the substances mentioned in section 1 are 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, they 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 5

The Federal Minister of the Interior is hereby empowered to issue a revised list, arranged in alphabetical order, of 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 6

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

Section 7

This Order shall enter into force on the day after the date of publication.

Bonn, 25 October 1961

LUDWIG ERHARD

for the Federal Chancellor

DR. SCHRÖDER

Federal Minister of the Interior

E/NL.1961/102

Bundesgesetzblatt

31 October 1961, No. 86, pp.1915 and 1916

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

25 October 1961

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:

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

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 26 September 1960 concerning the prescription of medicaments containing narcotic drugs and the dispensing of such medicaments in pharmacies (Bundesgesetzblatt I, p.769)**/2/ is hereby amended in the following respects:

1. A second sentence in these terms is added to section 7, paragraph 1:

"The foregoing provision does not apply to medicaments which contain substances mentioned in section 10a, paragraph 1, by themselves or in combination with a substance or preparation mentioned in section 9, paragraph 1, or section 10, paragraph 1."

2. Section 7, paragraph 2, shall read:

"(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. Levophenacetylmorphan
12. Metazocine
13. Myrophine
14. Norlevorphanol
15. Phenampromide
16. Phenazocine
17. Piminodine"

3. A new paragraph 3 in these terms is added to section 7:

"(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."

4. Section 8, paragraph 1, shall read:

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

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

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

5. Section 9, paragraph 1, shall read:

"(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. <u>Amphetamine</u>	0.2 g
8. <u>Amphetamine for use in the eye</u>	0.2 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>	0.2 g
15. <u>Diacetylmorphine</u>	0.2 g
16. <u>Diethylthiambutene</u>	0.2 g
17. <u>Dihydromorphine</u>	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>	0.2 g
23. <u>Dipipanone</u>	0.2 g
24. <u>D-moramide</u> [<u>dextromoramide</u>] ^{3/}	0.2 g
25. <u>Etixeridine</u>	0.2 g
26. <u>Hydrocodone</u>	0.2 g
27. <u>Hydromorphone</u>	0.2 g
28. <u>Hydroxypethidine</u>	0.2 g
29. <u>Isomethadone</u>	0.2 g
30. <u>Ketobemidone</u>	0.2 g
31. <u>Laudanum</u> or a preparation similar to laudanum	0.2 g
32. <u>Levomethorphan</u>	0.2 g
33. <u>Levomoramide</u>	0.2 g
34. <u>Lavorphanol</u>	0.2 g
35. <u>Methadone</u>	0.2 g
36. <u>Methylamphetamine</u>	0.2 g
37. <u>Methyldesorphine</u>	0.2 g
38. <u>Methyldihydromorphine</u>	0.2 g
39. <u>Methylphenylpiperidine</u> carboxylic acid esters (esters of 1-methyl-4-phenylpiperidine-4-carboxylic acid) except pethidine	0.2 g
40. <u>Metopon</u>	0.2 g
41. <u>Morpheridine</u>	0.2 g
42. <u>Morphine</u>	0.2 g
43. <u>Morphine aminoxide</u> (Morphine-N-oxide, genomorphine)	0.2 g

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

44.	<u>Narcophin</u>	0.2 g
45.	<u>Nicomorphine</u>	0.2 g
46.	<u>Normethadone</u>	0.2 g
47.	<u>Normorphine</u>	0.2 g
48.	Opium or the corresponding quantity of an opium preparation	0.2 g
49.	<u>Oxycodone</u>	0.2 g
50.	<u>Oxymorphone</u>	0.2 g
51.	Pantopon or a preparation similar to pantopon	0.2 g
52.	<u>Pethidine</u>	0.2 g
53.	<u>Phenadoxone</u>	0.2 g
54.	<u>Phenomorphane</u>	0.2 g
55.	<u>Proheptazine</u>	0.2 g
56.	<u>Properidine</u>	0.2 g
57.	<u>Racemethorphan</u>	0.2 g
58.	<u>Racemoramide</u>	0.2 g
59.	<u>Racemorphan</u>	0.2 g
60.	<u>Thebacon</u>	0.2 g
61.	<u>Trimeperidine</u>	0.2 g"

6. A new paragraph 5 in these terms is added to section 10a:

"(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."

7. Section 19, paragraph 4, shall read:

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

1. Name and address of the medical practitioner, dentist or veterinary surgeon;
2. 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 which contain substances mentioned in section 10 (a), paragraphs 1 to 3, 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 must state in the prescription, instead of the instructions for use, "For use in practice" or "For use in hospital".

8. Section 21, paragraph 7, shall read:

"(7) When dispensing medicaments which contain substances mentioned in section 10a, paragraph 1, or normethadone or diphenoxylate, in the form, composition and maximum doses specified in section 10a, paragraphs 4 and 5, the pharmacist

must note on the prescription the fact that the medicaments have been dispensed, as well as the date on which they were dispensed".

9. Section 29a shall read:

"Section 29a

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

Section 2

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

Section 3

This Order shall enter into force on the day after the date of publication.

Bonn, 25 October 1961

LUDWIG ERHARD

for the Federal Chancellor

DR. SCHRÖDER

Federal Minister of the Interior

E/NL.1961/103

Bundesgesetzblatt
31 October 1961, No. 86, pp.1911-1914

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^{***}/

26 October 1961

Pursuant to section 5 of the Second Order concerning substances placed on the same footing as narcotic drugs of 25 October 1961⁴/ (Bundesgesetzblatt I, p.1909), 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 amended by the aforesaid Order and by the Order concerning substances placed on the same footing as narcotic drugs dated 26 September 1960⁵ (Bundesgesetzblatt I, p.765).

Bonn, 26 October 1961

DR. SCHRÖDER

Federal Minister of the Interior

^{***}/ Concerns Bundesgesetzblatt III, 2121-6-8.
⁴/ Note by the Secretariat: E/NL.1961/101.
⁵/ Note by the Secretariat: E/NL.1960/122.

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>	(dl- α -methylphenethylamine)
9. <u>Anileridine</u>	(1- <u>para</u> -aminophenethyl-4-phenylpiperidine-4-carboxylic acid ethyl ester)
10. <u>Benzethidine</u>	(1-(2-benzyloxyethyl)-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> -chlorbenzyl-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-piperidine-3-heptanone)
25. <u>Dextromoramide</u>	((+)-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>Etixeridine</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>Hydromorphinol</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>Levophenacylmorphin</u>	((-)-3-hydroxy-N-phenacylmorphinan)
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. <u>Methylamphetamine</u>	

Short Name	Scientific Designation
40. <u>Methyldesorphine</u>	(6-methyl-delta 6-deoxymorphine)
41. <u>Methyldihydromorphine</u>	(6-methyldihydromorphine)
42. <u>Methylphenylpiperidine</u> carboxylic acid esters, (including <u>pethidine</u> and <u>properidine</u>)	
43. <u>Metopon</u>	(5-methyldihydromorphinone, originally described as 7-methyldihydromorphinone)
44. <u>Morpheridine</u>	(1-(2-morpholinoethyl)-4-phenylpiperidine-4-carboxylic acid ethyl ester)
45. <u>Myrophine</u>	(myristylbenzylmorphine)
46. <u>Norlevorphanol</u>	((-)-3-hydroxymorphinan)
47. <u>Normethadone</u>	(6-dimethylamino-4,4-diphenyl-3-hexanone)
48. <u>Normorphine</u>	(demethylmorphine)
49. <u>Oxymorphone</u>	(14-hydroxydihydromorphinone)
50. <u>Pethidine</u>	(1-methyl-4-phenylpiperidine-4-carboxylic acid ethylester)
51. <u>Phenadoxone</u>	(6-morpholino-4,4-diphenyl-3-heptanone)
52. <u>Phenampromide</u>	N-(1-methyl-2-piperidinoethyl) propionanilide
53. <u>Phenazocine</u>	(2'-hydroxy-5,9-dimethyl-2-phenethyl-6,7-benzomorphan)
54. <u>Phenomorphane</u>	(3-hydroxy-N-phenethylmorphinan)
55. <u>Phenoperidine</u>	1-(3-hydroxy-3-phenylpropyl)-4-phenylpiperidine-4- carboxylic acid ethyl ester
56. <u>Piminodine</u>	(4-phenyl-1-(3-phenylaminopropyl)piperidine-4-carboxylic acid ethyl ester)
57. <u>Proheptazine</u>	(1,3-dimethyl-4-phenyl-4-propionoxazacycloheptane)
58. <u>Properidine</u>	(1-methyl-4-phenylpiperidine-4-carboxylic acid isopropyl ester)
59. <u>Racemethorphan</u>	((±)-3-methoxy-N-methylmorphinan)
60. <u>Racemoramide</u>	((±)-4-(2-methyl-4-oxo-3,3-diphenyl-4-(1-pyrrolidinyl) butyl) morpholine)
61. <u>Racemorphan</u>	((±)-3-hydroxy-N-methylmorphinan)
62. <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>	Same
2. <u>Dihydrocodeine</u>	"
3. <u>Pholcodine</u>	2-morpholinylethylmorphine