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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

DENMARK

Communicated by the Government of Denmark

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.

BOARD OF PUBLIC HEALTH
Copenhagen, 1 July 1956

CIRCULAR WITH ANNEXES ON MEASURES TO COMBAT ADDICTION TO NARCOTIC DRUGS

In its report of June, 1953, the Ministry of Home Affairs Committee on the misuse of narcotic substances stressed the fact that to a large extent addicts seemed to be procuring their supplies of narcotics by means of medical prescriptions, which they sometimes obtained by giving false information to one medical practitioner after another.

The Committee recommended that, to prevent the occurrence of new cases of addiction through improper prescribing for patients and the persistence of existing cases through the use of improper prescriptions, detailed rules should be issued for the guidance of medical practitioners in prescribing narcotic substances.

In response to this recommendation, the Board of Public Health is issuing the above-mentioned directions, together with a collection of the requisite administrative regulations, as an annex to the Act of 24 May 1955^{1/}

In this connexion, it is felt essential to draw attention to the fact that, if a medical practitioner, without strong reason for doing so, fails to comply with the directions for the prescription of narcotic substances, does not keep an accurate record of his non-routine prescriptions, and, in addition, fails to take all reasonable steps to follow up the effects of the prescriptions and avoid undesirable consequences, he renders himself liable to withdrawal of the right to prescribe narcotic substances under article 5b of the Medical Practice Act, and in very serious cases may also be charged with a breach of article 18 of the Medical Practice Act.

With reference to article 5a(3) of Act No. 168 of 24 May 1955^{2/} amending the Medical Practice Act (cf. the official proclamation of the Act dated 9 August 1955), the Board of Public Health hereby declares that by narcotic substances for the purpose of the Act are to be understood the substances listed in the Board of Public Health Circular of 1 December 1952^{3/} on the prescribing and supply of medicaments, article 5 (cf. circular of 11 May 1954^{4/}) as amended by the Board of Public Health circular of to-day's date. These substances are the following:

1/ Note by the Secretariat: E/NL.1955/99.

2/ Note by the Secretariat: E/NL.1956/129.

3/ Note by the Secretariat: E/NL.1953/101.

4/ Note by the Secretariat: This text will be published as soon as it is received.

Amphetamine (Mecodrine)
Dexamphetamine (Dexedrine)
Diacetylmorphine (Heroin)
Hydrocodone^{5/} (Dilodide)
Hydromorphone (Dilaudide)
Ketobemidone (Ketogan, Cliradon)
Cocaine and drugs containing cocaine
(medicaments containing more than
0.1 per cent of cocaine)
Levomethorphan (Dromoran)
Methadone (Butalgin, Quodidone)
Methamphetamine (Euphadrin,
Chemodrine, Pervitine)

Morphine (medicaments containing more than
0.2 per cent of morphine)
Oxycon (Eucodal) [Oxycodone]^{6/}
Opium (medicaments containing the equivalent
of more than 1 gramme of opium)
Tinctures of opium (Tinctura opii) unmixed and
in any quantity
Pethidine (Dolantin)
Thebacon (Acedicone)
Ticarda [Normethadone]

In order further to combat the misuse of narcotic substances, all medical practitioners are urged (cf. the special rule in the Narcotic Substances Act, No. 169 of 24 May 1955, article 3(1), in fine) to keep a special morphine register in which the patients who receive prescriptions for narcotic substances will enter in their own handwriting their name, occupation and address. This precaution is to be taken in cases in which the medical practitioner is not certain of the patient's identity. In cases of doubt, medical practitioners are requested to consult the competent public health officer or the Board of Public Health in writing or by telephone.

Lastly, it should be observed that, in accordance with article 44 of the Pharmacies Act, narcotic substances are in general not available for public distribution.

The much stricter control of the use of narcotic substances in recent years and the consequent increased demand for doctors' prescriptions have resulted in a considerable rise in the number of forged prescriptions. The Board of Health has therefore found it necessary to make certain amendments to the regulations governing the prescribing and supply of narcotic substances. These amendments, which will be found in annex 3, can be briefly summarized as follows:

1. Since prescriptions for narcotic substances issued after the present circular comes into force will be retained by the pharmacist, such prescriptions should relate to narcotic substances only.
2. Whenever possible, prescriptions should be made out on a form bearing the name, telephone number and address of the medical practitioner printed or stamped on it (cf. article 1 of the circular).
3. Prescriptions by telephone will continue to be allowed where absolutely necessary (cf. paragraph 4 below).
4. Prescriptions presented for dispensing which do not bear printed particulars of the medical practitioner together with the patient's name and address and the quantity of the medicaments prescribed both in figures and in words (block letters) may not be dispensed unless the pharmacist by ringing back fully satisfies himself concerning the prescriber's identity and the genuineness of the prescription.
5. All prescriptions for narcotic substances must be cancelled immediately after dispensing and retained by the dispensing pharmacist.
6. Pharmacists must keep such prescriptions for two years.

Frandsen.

Skovgaard.

5/ Note by the Secretariat: Proposed or international non-proprietary names have been underlined.

6/ Note by the Secretariat: The words in square brackets have been inserted by the Secretariat.

CIRCULAR

Annex 3 ^{7/}

To all pharmacists, veterinary surgeons, midwives,
medical practitioners and dentists

Amendments to the Board of Public Health circular of 1 December 1952^{3/} on the prescribing and supply of medicaments, as amended by the circulars of 11 May 1954^{4/} and 10 November 1955^{4/}.

The introductory paragraph is deleted and replaced by the following:

"In pursuance of the Pharmacies Act, No.209, of 11 June 1954, article 26 (2) and article 41, the Board of Public Health hereby makes the following changes in the regulations for the writing and dispensing of prescriptions."

Article 2(1) is deleted and replaced by the following:

"A prescription should normally be written on a special form for the purpose printed or stamped with the name, profession, address and telephone number of the prescriber.

"Only one side of the prescription form may be used for the prescription of medicaments."

Article 2(2), third sub-paragraph. This is deleted and replaced by the following:

"Weights may be given only in grammes, milligrammes and microgrammes. The official abbreviations g, mg and μ g may be used.

"Decimal fractions should not contain a zero after the decimal point.

"If the prescription is of the type of which a copy is to be taken under the terms of article 5, the prescriber shall state the quantity of the medicament prescribed in both figures and words (block letters)."

Article 2(6), first sub-paragraph. This is deleted and replaced by the following:

"The prescriber shall always specify the person or animal for whom or for which the prescription is issued. The address of the patient or the name and address of the owner of the ailing animal shall be stated. When the prescription is of the type of which a copy is to be taken under the terms of article 5, the prescription shall not be dispensed if the above-mentioned requirements are disregarded (but cf. article 5(4))."

Article 3(1), second sub-paragraph. This is deleted and replaced by the following:

"Particularly in the case of prescribing by telephone of medicaments coming under article 5 (narcotic substances, etc.), the person receiving the prescription shall, by ringing back or in some other manner, fully satisfy himself concerning the identity of the person prescribing unless that person is directly known to the person receiving the prescription."

^{7/} Note by the Secretariat: Annexes 1 and 2 have already been published as documents E/NL.1955/99 and E/NL.1956/129 respectively.

Article 5 is deleted and replaced by the following:

"1. A copy shall be made by the pharmacy of all prescriptions and orders for medicaments containing:

Amphetamine (Mecodrine)
Dexamphetamine (Dexedrine)
Diacetylmorphine (Heroin)
Hydrocodone (Dicodide)
Hydromorphone (Dilaudide)
Ketobemidone (Ketogan, Cliradon)
Cocaine and drugs containing cocaine (medicaments containing more than 0.1% of cocaine)
Levomethorphan (Dromoran)
Methadone (Butalgin, Quotidone)
Methamphetamine (Euphadrin, Chemodrine, Pervitine)
Morphine (medicaments containing more than 0.2% of morphine)
Oxycon (Eucodal) /Oxycodone/
Opium (medicaments containing the equivalent of more than 1 gramme of opium)
Tinctures of opium (Tinctura opii) unmixd and in any quantity
Pethidine (Dolantin)
Thebacon (Acedicone)
Ticarda /Normethadone/

"2. The copies shall be made on forms issued by the Board of Public Health and shall be sent monthly not later than eight days after the end of the month to the county medical officer of health (in Copenhagen, the city medical officer of health).

"3. All prescriptions issued after the entry into force of this circular and relating to the medicaments mentioned in the present article, of which a copy must be made, shall be cancelled and retained by the pharmacist. Except for sickness insurance prescriptions or the like, the prescriptions in question shall be kept by the pharmacist for at least two years.

"4. The fact that a prescription for the medicaments mentioned in the present article does not fulfil the requirements specified in article 2(1), (2) and (6) of the present circular shall suffice to bar the dispensing of the prescription unless the prescriber's identity and the genuineness of the prescription are fully established by ringing back.

"5. Preparations, of the prescription for which a copy has to be taken, may not be supplied by pharmacies to distributing medical practitioners for further distribution unless the medical practitioner in question has been given express permission to dispense such preparations by the Ministry of Home Affairs. So far as veterinary surgeons are concerned, reference is made to the provisions of the Ministry of Agriculture Notice of 1 November 1955 concerning the purchase, distribution and dispensing of medicaments for animals by veterinary surgeons."

Article 7(3), fourth line: The words "that name shall be shown" are replaced by the words "only that name may be shown".

Article 7(4). This is deleted and replaced by the following:

"Except as otherwise permitted in individual cases by the Board of Public Health, no designation, strength or composition may be indicated on the label of a medicament other than that corresponding to the medicament prescribed. This provision shall apply even though the prescriber has expressed a wish to the contrary".

Article 9(2), is deleted and replaced by the following:

"Medicaments in Group B may be supplied as many times and at such intervals as the

prescriber has indicated for as long as the prescription is valid (see, however, article 6(4)).

"If the prescriber has not indicated how many times or at what intervals a medicament may be supplied, the medicaments in this group may be supplied not more than five times."

Article 9(3), is deleted and replaced by the following:

"Medicaments in Group C may be supplied without restriction for as long as the prescription is valid (see, however, article 6(2))."

Article 9: The following is added as a new paragraph 4:

"The dispensing of prescriptions containing medicaments listed in more than one of Groups A, B and C shall be governed by the provisions applicable to the first of such groups."

Article 15, first line:

The words "or owner" are inserted after the word "master".

Article 17, paragraph 2, last sub-paragraph: This is deleted and replaced by the following:

"The mixtures referred to may, on the prescription of a medical practitioner and subject to compliance with the aforesaid provisions, be supplied to sanatoria and nursing institutions, including work institutions, children's homes and the like. Where alcoholic mixtures are prescribed for the common use of a number of patients in the aforesaid institutions, the quantitative restrictions on their supply mentioned above shall no longer apply."

"Pharmacies may not supply the alcoholic mixtures (solutions) mentioned in paragraph 2, first sub-paragraph, to distributing medical practitioners or to distributing or dispensing veterinary surgeons for further distribution."

Article 18, paragraph 2, first line:

"one litre" is amended to "two litres".

Article 18, paragraph 3, first line:

The words "or owner" are inserted after the word "master".

This circular shall enter into force immediately.

Frandsen

/Skovgaard.

Annex 4

RULES FOR THE GUIDANCE OF MEDICAL PRACTITIONERS

The rules relate to the following groups of substances:

- A. Morphine and preparations containing morphine (including tetraon), and synthetic substances with similar effects, including Hydromorphone (Laudacone, Dilaudid), oxycon /Oxycodone/ (Eucodal), Thebacon (Acedicone), Pethidine (Dolantin), Methadone (Butalgin), Ketobemidone (Cliradon), methorphan /Racemorphan/ (Dromoran), Metopon and ketogan.

These substances are hereinafter referred to as "morphine, etc.".

- B. Tinctura opii.
- C. Codeine and ethylmorphine.
- D. Hydrocodone (Dicodide).
- E. Cocaine.
- F. Amphetamine (Mecodrine), metamphetamine (Euphadrin) and similar preparations.
- G. Sleeping drugs.

There can be no justification for the use of diacetylmorphine (heroin)^{1/}

All the above-mentioned substances can induce addiction.^{2/} The danger of this is not so great in the case of codeine, ethylmorphine, hydrocodone and sleeping drugs, but it still exists.

The danger of addiction is always greatest when the substances are administered by injection and less when they are administered per os. In cases of diarrhoea, for example, moderate doses of tinctures of opium can be administered per os over a long period without leading to habit-formation but, even here, caution is necessary in determining the dosage.

The following directions have been prepared with the medical practitioner's prescriptions for persons other than himself in mind. It should, however, be emphasized that a medical practitioner should display at least the same degree of caution in prescribing for himself as he should show according to the directions in corresponding prescriptions for his patients.

^{1/} The manufacture of heroin in Denmark is prohibited, and prohibition of its import may also be expected.

^{2/} By addiction is understood a condition caused by the frequent and continued absorption of a narcotic substance and characterized by: (a) a strong feeling of well-being after absorption of the substance, especially in the initial stage, (b) a craving for the substance, and various forms of malaise when the supply is interrupted, (c) a tendency to increase the size of the dose, in some cases symptomatic of habituation, i.e. diminished sensitivity to the substance due to its continued absorption, (d) a propensity to relapse after treatment.

Addiction to narcotic drugs often has as deep-seated cause a defect of character, which may be of various kinds, but which most often takes the form of inability of the individual to adapt himself to the realities and demands of life.

Persons who feel the need for morphine, etc., because of pain, need not, therefore, necessarily be addicts, even if they develop habituation, as evidenced by the steadily larger doses that have to be given to still the pain.

I

Prescriptions for persons other than regular patients of the
medical practitioner (including prescriptions by medical
practitioners on night duty)

1. There is no justification for issuing prescriptions for morphine, etc., Hydrocodone and amphetamine, etc. (groups A, D and F).

The danger that withdrawal symptoms in morphine addicts and other persons who are obviously addicted to narcotic drugs may endanger the life and health of such persons is very small in comparison with the harm which may be caused by supplying addicts with the drugs in question.

In certain cases it may, however, be necessary for the medical practitioner, after examination on the spot, to give a person unknown to him a single injection of morphine, etc. (group A) or a prescription for one or more oral doses of morphine, etc. (A) or of hydrocodone (D), but not of amphetamine (F).

2. Tinctura opii, codeine and ethylmorphine, oculoguttæ cocaini and sleeping drugs (groups B, C, E and G).

These preparations may, according to the circumstances, be prescribed for persons who are not among the medical practitioner's regular patients. Nevertheless, such preparations must at all times be prescribed in only very limited quantities and solely where there is reasonable indication for their use (cf. section II below), and usually only after examination of the patient.

In the municipalities of Copenhagen and Frederiksberg, where unidentified morphine addicts can often prove particularly troublesome to medical practitioners, the assent of hospital administrations has been obtained to an arrangement whereby such persons can be referred at any time to the medical officer on reception duty at the Copenhagen Municipal Hospital or the duty physician in the psychiatric ward of the Frederiksberg hospital, with an eye to the advisability of their being temporarily detained in hospital.

II

Prescriptions for a medical practitioner's regular patients who are
not addicted to narcotic drugs

Group A, morphine, etc.

In cases of acute and possibly recurring pain, morphine, etc., should only be prescribed in such small quantities in each prescription that the medical practitioner can carefully supervise the consumption of morphine and intervene when addiction threatens to develop.

Morphine, etc., should not normally be used for such conditions as menstruation pain, migraine and the like.

In disorders complicated by cor pulmonale (asthma and other lung ailments), morphine etc., when administered in doses of over 10 mg, after the absorption of quite large quantities of alcohol or sleeping drugs, can produce a mortally dangerous condition.^{3/}

In cases of chronic illness morphine, etc., should usually be continuously prescribed only when the quo ad vitam prognosis for so long as can be foreseen is hopeless.

^{3/} The experience of recent years has shown that in doses of 20 - 30 mg morphine has not seldom caused fatal poisoning in persons who had previously taken alcohol or sleeping drugs without any marked effect. Experience has also shown that the absorption of large quantities of barbituric acid by persons under the influence of alcohol, especially when they are administered intravenously, can also cause mortally dangerous poisoning.

In certain cases of chronic pain with a good quo ad vitam prognosis (e.g. tabes, causalgia, arachnoiditis, angioneurotic pain), morphine, etc., may nevertheless be indicated, but the medical practitioner must keep the patient down to the lowest possible consumption. Switching to other medicaments may be helpful. In such cases, the medical practitioner must ascertain to what extent an induced addiction may be regarded as a lesser evil for the patient than unbearable pain. He should also have the patient examined by a specialist colleague.

Group B, tinctura opii.

The danger of addiction is less than in the case of morphine, etc. (Group A).

Nevertheless, in using tinctura opii in cases of chronic diarrhoea, the danger of causing addiction should be taken into account, and the same applies to an even greater extent where the substance is used in cases of depression.

Group C, codeine and ethylmorphine

Doses of these medicaments used as cough medicine only seldom lead to addiction; the medical practitioner should nevertheless be on guard if the patient often asks for large quantities of the substances in question.

Group D, Hydrocodone (Dicodide)

From the point of view of causing addiction, this substance occupies an intermediate position between codeine and morphine.

Group E, cocaine.

Oculoguttae cocaini should be prescribed only for patients with diagnosed diseases of the eye, for which use of the substance is indicated, and then only in suitably small quantities. There should be no other prescription of cocaine for the patient's own use.

Group F, amphetamine, etc.

Solutions of these preparations for injection should be reserved for use in hospitals. Requests from patients for prescriptions for such injection solutions will practically always mean that the persons in question are either themselves addicted to the substances or intend to pass the preparations on and perhaps sell them to addicts.

Cases in which the oral administration of these substances is medically indicated are very few: narcolepsia, certain cases of Parkinson's disease and enuresis nocturna, and a few others.

Despite the fact that amphetamine, etc., are recommended in other countries (particularly the English-speaking countries) as an effective slimming agent, in Denmark, where the misuse of amphetamine, etc., is considerable and widespread, the same extreme caution should be shown in prescribing amphetamine, etc. for this purpose as for any other use of the substances.

Amphetamine, etc., have been quite commonly used against lassitude. An emphatic warning must be given against this practice. In cases of constitutional asthenia and lassitude resulting from illness (neurasthenia e labore, post-infective and post-operative lassitude, lassitude during convalescence, in cases of depression and the like), the use of amphetamine is irrational and harmful, because the patient is stimulated to overtax his strength thereby retarding his recovery. For physiological lassitude, amphetamine should be used only exceptionally, because in such cases the danger of habit-formation is particularly great.

Group G, sleeping drugs

Some persons make such serious abuse of sleeping drugs that they become addicts, taking the drugs not in order to induce sleep but to induce euphoria throughout the day. This form of addiction to sleeping drugs is often combined with addiction to amphetamine and similar drugs.

Apart from the prescription of sleeping drugs for agitated mental patients and of phenobarbital for epileptics, care should always be taken to ensure, in cases where sleeping drugs are prescribed continuously, that the patients in question receive only such doses as may be considered reasonable for the treatment of their insomnia.^{4/}

If the medical practitioner suspects that a person is using conspicuously large quantities of sleeping drugs, he should keep a careful account of the dates of the prescriptions and the quantities prescribed.

III

Prescriptions for cases combining chronic illness and drug addiction among a medical practitioner's regular patients

The directions for the treatment of these patients will be substantially the same as those given in section II for patients suffering from chronic illness but not addicted to drugs.

IV

Prescriptions for a medical practitioner's regular patients who are to be regarded as suffering from drug addiction alone

1. Morphine, etc., tinctura opii and Hydrocodone (groups A, B and D)

Generally speaking, it must be taken that there is no justification for prescribing these substances for addicts of morphine and other drugs unless the prescription forms part of a systematic treatment to cure addiction, or represents an interim measure until such time as the treatment can be started.

The substances in question (even in solution for injection) must in future be prescribed only in isolated cases as part of a definite and systematic attempt to cure addiction (since, however, such attempts usually fail when the case is given ambulant treatment, they should not be of a protracted nature), or where it is explicitly agreed between the medical practitioner and the patient that the patient will enter hospital by a specified date for treatment to cure his addiction. During the time which, on account of the patient's work, economic circumstances or other practical considerations, must elapse before the patient can enter hospital, the medical practitioner should try to keep the dose as low as possible and keep an exact account of the dates of the prescriptions and the quantities prescribed. The medical practitioner must report on such patients to the county medical officer of health (in Copenhagen the city medical officer of health) giving the patient's name and address and stating the nature and frequency of the prescriptions and the quantities prescribed.

If the patient fails to enter hospital as agreed by the specified date, or otherwise refuses to follow any instructions the medical practitioner may give in connexion with the above, the medical practitioner should refuse henceforth to prescribe for him the substances in question, in accordance with the general rule that if a patient refuses to follow the instructions for treatment given him by a medical practitioner he must take the responsibility for the consequences. The medical practitioner should also report the matter to the county medical officer of health (in Copenhagen to the city medical officer of health).

2. Codeine and ethylmorphine, cocaine and amphetamine, etc. (Groups C, E and F)

Putting a sudden stop to the taking of these substances by addicts, though causing them to suffer from acute malaise, produces no severe abstinence symptoms properly so-called; consequently a protracted, gradual withdrawal of these substances is not necessary.

^{4/} Cf. note 3 on the danger of administering large quantities of barbituric acid to persons suffering from alcoholic intoxication.

It should therefore be considered a general rule that in no case is there any justification for prescribing these substances for persons who are to be regarded as suffering from addiction alone.

3. Sleeping drugs (Group G)

To persons addicted to sleeping drugs, the same rules as in section IV, 1 apply *mutatis mutandis*.

Special care must be exercised in dealing with patients who have been in hospital for disintoxication treatment and who have been discharged as cured. It must be regarded as a gross professional error to begin prescribing morphine, etc., for such patients.

In cases of addiction of very long standing, the continued prescription of narcotic substances must be conditional on prior consultation of the medical officer of health on the result of any hospital treatment.