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LAWS AND REGULATIONS

PROMULGATED TO GIVE EFFECT TO THE PROVISIONS OF
THE INTERNATIONAL TREATIES ON NARCOTIC DRUGS AND PSYCHOTROPIC SUBSTANCES

NORWAY

Communicated by the Government of Norway

NOTE BY THE SECRETARY GENERAL – In accordance with the relevant Articles of the International Treaties on Narcotic Drugs and Psychotropic Substances, the Secretary-General has the honour to communicate the following legislative texts.

INDEX

E/NL.1976/143

ROYAL ORDER

dated 19 February 1965

EMBODYING REGULATIONS GOVERNING THE PRESCRIBING OR ORAL REQUISITIONING OF MEDICAMENTS FROM AND THE ISSUE OF MEDICAMENTS BY PHARMACIES

AS LAST AMENDED ON 15 MARCH 1976

I. Pursuant to: the Act of 29 April 1927 concerning the rights and duties of medical practitioners, section 5; the Act of 29 April 1927 concerning the rights and duties of dental surgeons, section 5; the Act of 10 December 1948 concerning veterinary surgeons, section 8; the Act of 21 June 1963 concerning the conduct of pharmacies, section 32; and the Act of 20 June 1964 1/ concerning medicaments and poisons, sections 20 and 21, Regulations governing the prescribing or oral requisitioning of medicaments from and the issue of medicaments by pharmacies are hereby made in accordance with a tabled draft.

II. The Ministry of Social Affairs is hereby empowered to make amendments and additions to the Regulations.

1/ Note by the Secretariat: E/NL.1966/51.

III. The Regulations shall enter into force on 1 April 1965.

The Regulations governing the prescribing or oral requisitioning of medicaments from and the issue of medicaments by pharmacies, of 27 September 1957, shall lapse as of the same date.

The draft reads as follows:

I. GENERAL PROVISIONS

Section 1. Definitions

1. The term "medicaments", as used in these Regulations, means substances, drugs and preparations which are prescribed or orally requisitioned from or issued by pharmacies to be used for the purpose of preventing, treating or alleviating sickness or pain in humans or animals or for internal use or external application in diagnosing sickness.

2. Medicaments for internal use or for external application:

Essentially, the scientific medical definition given in the pharmacopoeia determines the differentiation between medicaments for internal use and medicaments for external application.

The term "medicaments for internal use" means medicaments intended to be introduced into the body, into or through skin or mucous membranes, to be introduced behind the lips, into the nostrils, into the excretionary aperture of the lacteal gland, into the urethral orifice, into the "os uteri", into the anal ring a/ and into the conjunctival sac, and also medicaments intended to be applied in tissues or cavities which are opened in the course of an operative intervention and are surrounded by serous membranes.

All other medicaments are to be regarded as medicaments for external application. Nevertheless, for the purposes of these Regulations the following groups of medicaments shall always be deemed to be medicaments for external application:

(a) Ointments (unguenta and oculenta);

(b) Collyria;

(c) Medicaments for local application in the buccal cavity and throat: gargles; mouth washes, brush-applied medicaments (paints); medicated dentifrices; tooth-drops;

(d) Haemorrhoidal suppositories.

3. Prescription: A written requisition made out by a medical practitioner, a veterinary surgeon or a dental surgeon for one or more medicaments to be issued by a pharmacy for the use of particular persons or animals or for use in the practice of the issuer of the prescription or in a hospital or the like.

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a/ Regulation of 31 March 1965.

Where nothing to the contrary is expressly required by law or regulation, the validity attaching to a prescription likewise attaches to an order given by telephone in conformity with the rules stated in section 5, and to a verbal requisition made personally by a medical practitioner, a veterinary surgeon or a dental surgeon.

4. Prescription medicaments: Medicaments which, where nothing to the contrary is expressly required by law or regulation, may be supplied by a pharmacy only against a prescription issued by a medical practitioner, a veterinary surgeon or a dental surgeon.

5. Renewal: An entry by the medical practitioner or the veterinary surgeon on the prescription to the effect that the medicament may be issued several times.

6. "Over-the-counter" issue: The issue of medicaments or other goods by pharmacies otherwise than against a prescription or other form of requisition (cf. sections 15-19).

II. REQUISITIONING OF MEDICAMENTS

Section 2. Prescription medicaments

Prescription medicaments b/ are listed in the schedule valid at the time which are marked with one or other of the letters A, B, C and D. The Director, Office of Health, shall determine whether a medicament shall be obtainable only against a prescription and to which group it shall belong.

Every preparation containing a prescription medicament shall likewise be obtainable only against a prescription unless it has been specifically exempted from that requirement. Medicaments intended for injection shall, whatever they may contain, invariably be obtainable only against a prescription.

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Section 3. c/ Validity of prescriptions

A prescription or renewal of a prescription shall be valid for up to one year from the date of issue or renewal of the prescription.

A prescription for medicaments of:

Group A may be filled once only and may not be refilled. A verbal requisition given otherwise than in the form of a telephone order shall not be valid (cf. section 1, para. 3);

Group B may be filled once and may not be renewed more than once;

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b/ Regulation of 20 January 1966.

c/ Regulation of 16 September 1974.

2/ Note by the Secretariat: Those sections not relevant to narcotic drugs or psychotropic substances have been omitted.

Group C may be filled once and may be renewed more than once; and

Group D may be filled more than once within the year following its issue.

The issuer of a prescription may restrict its validity by a special annotation. The intention must in such a case be made clearly apparent by the use of such annotations as: "Non-repeatable"; "To be issued not more than twice"; or the like.

Section 4. Making out of prescriptions

1.[d/] A prescription shall be written on a form on which the name, occupation, address and telephone number (if any) of the issuer of the prescription are printed or stamped or on which these particulars are typed or are entered in block letters. The particulars shall be sufficiently complete to prevent confusion with other issuers of prescriptions.

A prescription for medicaments of group A shall be made out on a special form authorized by the Office of the Director of Health for the individual issuer of prescriptions.

Prescription forms shall be supplied against a written order. A special prescription form shall not be used for prescribing medicaments of group A for use in hospitals or the like.

2. The prescription shall be written clearly and distinctly, shall be dated as of the date on which it is made out, and shall be signed personally by the issuer.

3.[cd/] As a rule, the name of the person for whom the medicament is intended shall be indicated. If the patient is less than 16 years of age, his age shall be entered. A prescription for medicaments of group A shall invariably state the given name or names, surname, exact date of birth and complete address of the patient.

If the patient is not known to the issuer of the prescription, production of proof of identity shall be required before a prescription for a medicament of group A or group B is made out.

Medicaments for the use of more than one person shall not be prescribed on the same prescription form.

4. The name or composition of the medicament and the quantity thereof shall be indicated in such a way that the prescription can be filled, without special instructions, by any pharmacy in the country.

When medicaments of group A are prescribed, the quantity shall be stated both in figures and in words.

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d/ Regulation of 26 January 1976, to enter into force on 1 July 1976.

Prescription medicaments shall be prescribed only in the form of preparations ready for use. Dry-substance ampoules, and likewise certain medicaments intended for dilution (e.g. diluenda), are excepted. The nature and quantity of the solvent or diluent shall as a rule be indicated (concerning sublimates, see section 14, para. 2).

Medicaments other than medicaments of group A may not be prescribed on a prescription on which medicaments of group A are prescribed.

5. Complete directions for use, indicating both the single dose and the daily dose, shall be entered on the prescription in all cases where it is possible to do so; e.g.: "1 tablet (1 tablespoonful) three times a day". If it is not possible to state the exact dosage on the prescription, the prescription shall bear the words: "Dosage notified to patient".

Where a medicament is prescribed f/ in an "ad hoc" preparation in a single or daily dose exceeding the maximum dose laid down for the medicament in Annex II, the dosage shall be written both in figures and in words; e.g.: "1 - one - teaspoonful 3 - three - times daily".

Concerning medicaments for use in a hospital or in a practice, see paragraph 9.

6. c/ To be valid, renewal (cf. section 3) shall be written both in figures and in words. The renewal shall apply only to the medicament under whose name it is entered, and not to other medicaments prescribed on the same prescription form.

7. A prescription for medicaments or other goods which are required immediately shall bear the inscription "CITO"; "Urgent", or the like.

8. Where a medicament is prescribed which is intended for injection and this is not apparent from the name of the medicament (injectabile, infundibile), the words "For injection" shall be entered on the prescription.

9. d/ Where medicaments of group A are prescribed for use in a hospital or the like, ordinary prescription forms shall be used. (See this section, para. 1).

Where medicaments are prescribed for use in a hospital or the like or for use in the practice of the issuer of the prescription, the name of the institution or the words "For use in the practice", or the like, shall be entered on the prescription instead of the name and address of the patient.

The provisions in this section, para. 5, concerning directions for use shall not apply.

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f/ Regulation of 15 March 1974.

10.[d] A prescription issued by a veterinary surgeon shall be headed "Medicament (or "Medicaments) for animals", or "V.M.". Instead of the patient's name, the name of the animal's owner and of the kind of animal shall be entered. Where medicaments of group A are prescribed, the first name or names, surname, date of birth and address of the owner shall be entered.

Section 5. Telephoned prescriptions

The requisitioning of medicaments by telephone shall be performed in conformity with the provisions of section 4 concerning the making out of prescriptions.

In addition, the following rules shall apply:

1. The issuer of the prescription shall himself telephone the order, which shall be taken down at the pharmacy by a person entitled to dispense prescriptions.

2.[d] The prescription shall be dictated clearly and distinctly and at a speed such that the receiver thereof can enter the prescription directly into the pharmacy's telephoned-prescription copy-book. When the prescription has been written down, the receiver thereof shall read over to the issuer of the prescription what has been so written, to ensure that the prescription has been correctly understood.

In the case of medicaments of group A, only the smallest standard package, or a quantity corresponding to three days' doses (ordinary therapeutic doses), may be ordered.

3. The person receiving the telephoned order shall immediately enter on it the name of the issuer of the prescription, the date, and his own signature.

4.[d] If there is room for doubt as to the identity of the issuer of the prescription the person receiving it shall, before the medicament is issued, verify by a telephone call or by other means that the issuer of the prescription is the person that the caller claimed to be. Special caution shall be observed in dealing with telephoned orders for medicaments of group A and other medicaments which experience has shown to be liable to incite misuse, e.g. certain hypnotics and sedatives. If the issuer of the prescription cannot be reached by telephone at his own business or private telephone number for the purposes of such verification, the person who collects medicaments of group A shall if he is not known to the pharmacy be required to produce credentials and if necessary written authority before the medicaments are handed over.

5. A telephoned prescription may be filled only once. The same shall apply to a telephoned order for the renewed filling of an invalid prescription.

6. The pharmacy's copy-book for telephoned prescriptions shall be produced when the pharmacy is inspected and shall be kept for three years after the date of the last entry in it.

Section 6. Right of requisition

The right to prescribe prescription medicaments vests in medical practitioners, veterinary surgeons, and dental surgeons possessing the right to exercise their profession in Norway.

The right g/ to requisition prescription medicaments from the main store of a hospital also vests in persons having a recognized pharmaceutical training.

A limited right to requisition prescription medicaments also vests in:

Midwives in respect of the substances named in section 10 and in conformity with the rules there set forth;

Masters h/ of ships, fishing and whaling or sealing vessels, or aircraft, and shipping companies, in conformity with the rules set forth in section 11;

Firms h/ which are licensed by the Ministry of Social Affairs to requisition ready-packed medicine chests and the like for inflatable life-saving rafts, cf. section 11.

Section 7. Right of requisition vested in medical practitioners

1. The right of a medical practitioner to requisition prescription medicaments extends solely to medicaments for use in human medicine.

2. Medical students, alien medical practitioners and other persons who have obtained permission from the Ministry to serve as subordinate medical practitioners in a hospital or as assistants to a medical practitioner in his practice may requisition medicaments in conformity with the provisions of section 4 concerning the making out of prescriptions.

   Medicaments may be requisitioned only to the extent to which they are necessary for the performance of the duties of a subordinate medical practitioner attached to a hospital or of an assistant. The prescription shall be written out on a prescription form of the hospital or of the medical practitioner.

   The right of requisition d/ shall not extend to medicaments of group A.

3. Finnish and Swedish public medical practitioners in frontier areas have a general licence to practise medicine in adjacent medical districts of Norway, and may requisition medicaments for use in human medicine in conformity with the provisions of section 4 concerning the making out of prescriptions.

   An d/ authorized form shall not be required for medicaments of group A.

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g/ Regulation of 20 January 1969.

h/ Regulation of 19 December 1969.

Section 8. Right of requisition vested in veterinary surgeons

1. The right of a veterinary surgeon to requisition prescription medicaments extends solely to medicaments and the like for the treatment of animals or for controlling the spread of transmissible diseases of animals, and to substances for putting down domestic animals, when such medicaments or substances are requisitioned for use in the veterinary surgeon's practice.

2.[i] Veterinary students who have obtained the permission of the director of the veterinary service to perform short-term locum-tenens or assistant service in the establishment of a practising veterinary surgeon, and veterinary students who are in their last term at one of the institutes of the Veterinary College of Norway which operate an ambulatory practice, may requisition medicaments in conformity with the provisions of section 4 concerning the making out of prescriptions. Medicaments may be requisitioned only to the extent to which they are necessary for the performance of the service which the student is performing.

The prescription shall be written out on a prescription form of the veterinary surgeon in whose practice the student is serving, or on a special prescription form bearing the printed names of both the College and the institute and issued to the student by the governing body of the institute concerned.

Section 9.[j] Right of requisition vested in dental surgeons

The following rules, in addition to the provisions of sections 4 and 5, shall govern the requisitioning of medicaments by dental surgeons:

1. Prescription medicaments may be requisitioned only to the extent to which they are necessary for the exercise of the profession of dental surgeon or for patients in connexion with dental treatment.

2. Of the medicaments of group A, preparations containing methadone, morphine, pethidine and thebaicin may be requisitioned.

Preparations of group A which contain other narcotics may not be requisitioned.

3. The following prescription medicaments may be requisitioned for patients:

(a) Medicaments for local application on or in the teeth or on adjoining tissue, buccal mucous membrane or lips.

(b) Approved preparations for use in the prophylaxis of caries.

(c) Medicaments with a special application:

Metronidazole.

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i/ Regulation of 12 May 1969.

j/ Regulation of 30 December 1971.

(d)[k/] Medicaments in the following therapeutic groups in the register of therapeutic chemical medicaments of Norsk Medisinaldepot ("Norwegian Medicinal Depot"):

A 01 Oral and dental preparations not referred to under paragraph 3 (b);

A 03 Spasmolytics and anticholinergics;

A 04 Antiemetics;

D 04 Antihistamines;

J 01 Antibiotics for systemic use;

J 03 Chemotherapeutic agents for systemic use;

M 03 Muscle-relaxing agents;

N 02 Analgesics in dosed form for oral and rectal administration.

Analgesics with narcotics, not more than 20 pieces;

cf. paragraph 2 (medicaments of group A).

N 05 C Hypnotics and sedatives in dosed form, not more than 10 pieces.

R 01 Rhinological medicaments.

R 02 Pharyngological medicaments.

R 05 Medicaments for the treatment of coughs and colds.

(e) Repetition of prescriptions for medicaments of group 3 (a) and 3 (b) is permitted.

4. The following may be requisitioned for use in the surgery:

Prescription medicaments, subject to the restriction defined in paragraph 2.

In addition, cocaine may be requisitioned.

Of the medicaments of group A containing methadone, morphine, pethidine and thebaicin, not more than 20 tablets, powders, suppositories or ampoules, or in capped sterilizing flasks not more than 20 ml, may be requisitioned at one time.

5.[k/] Medicaments for parenteral administration to bring about general sedation, analgesy or general anasthesia may be used only by special permission of the Director, Office of Health.

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k/ Regulation of 25 October 1973.

6. In special cases the Director, Office of Health, may consent to the requisitioning of sodium fluoride substances for supply to larger publicly-owned school dental clinics, subject to conditions to be determined.

7. The Director, Office of Health, may on application grant a dental surgeon a wider right of requisition.

8. In cases of doubt the Director, Office of Health, may determine what medicaments are covered by the right of requisition.

Section 10. Right of requisition vested in midwives

Midwives may requisition the following substances for use in their practice:

Sublimates in the form of solutions or of solution-tablets.

Phenol, liquefied.

A written requisition shall be issued, showing the midwife's name and address, the quantity requisitioned, the midwife's personal signature, and a declaration that the disinfectants will be used only in the midwife's practice and will be stored in a responsible manner.

The midwife must be able to produce proof of identity if so required.

Section 11.[h] Right of requisition vested in masters of ships, fishing, whaling or sealing vessels, or aircraft, and shipping companies, etc.

Masters of water-craft and aircraft as referred to above, and shipping companies, may requisition medicaments, etc., in conformity with the regulations and approved lists in force.

A firm licensed thereto by the Ministry of Social Affairs, may requisition ready-packed medicine chests and the like for inflatable life-saving rafts.

III. ISSUE OF MEDICAMENTS AGAINST PRESCRIPTIONS OR OTHER FORMS OF REQUISITION

Section 12. Filling of prescriptions

1. The right personally to fill a prescription shall vest only in persons possessing an approved pharmaceutical training.

2.[d] Where a prescription is made out in conformity with the provisions of section 4, or doubt exists as to the interpretation of the prescription, or there are grounds for assuming that the issuer of the prescription has committed an error in making it out, the medicament may not be issued until the pharmacy has conferred with the issuer of the prescription and obtained the necessary elucidations. If it is possible to doubt that a prescription

is genuine, the doubt must be cleared up by a telephone call or by other means before the medicament is issued. If it is possible to doubt that the particulars regarding the patient are correct, the doubt must be cleared up by the production of proof of identity and if necessary of written authority issued to the person collecting the medicament, or by other means, before the medicament is issued.

3. Medicaments containing narcotics, barbituric acid derivatives or the like may, in cases where they are likely to be misused, not be issued until the pharmacy concerned has conferred with the issuer of the prescription.

4. If a prescription is marked "Cito" or with some similar expression it shall be filled as quickly as possible unless circumstances as referred to in paragraph 2 arise.

5. Where it seems indicated and the issuer of the prescription cannot be contacted the pharmacy may by way of exception dispense medicaments once only under a prescription which has become invalid or does not bear adequate directions for use. Dispensing in the circumstances aforesaid is subject to the condition that no greater quantity of the medicament shall be dispensed than is necessary pending contact with the issuer of the prescription, or, in the case of medicaments for which maximum doses have been prescribed, no greater quantity than that corresponding to the prescribed maximum day's dose for the patient.

   Quantities so dispensed shall be recorded on the prescription.

6. The name of the pharmacy shall be stamped, and the price of the medicament entered, on the prescription. Where for making up medicaments accessory substances have been used which were not prescribed by the issuer of the prescription, the names and quantities of those substances shall be entered on the prescription.

   Note: In pricing medicaments prepared or dispensed by the pharmacy the calculation of the price shall be entered on the obverse of the prescription.

7. A prescription for medicaments which may be issued only a limited number of times shall be dated and personally signed by the dispenser each time it is filled. If one prescription is required to show particulars of filling in respect of several medicaments, the entries thereon shall clearly show which medicament was or medicaments were dispensed on each occasion.

8. Prescriptions for medicaments of group A shall be retained after dispensing. They shall be kept for three years and shall on demand be forwarded to the Office of the Director of Health for verification. Telephone prescriptions for such medicaments shall be kept in the same way.

Section 13. General provisions concerning the signature

1.[l] A white signature shall be affixed to medicaments at the time of their issue. The signature applied to a medicament for injection shall bear a red diagonal stripe proceeding from the lower left-hand corner. The Director, Office of Health, may make exceptions to this rule.

2. The following shall be entered clearly on the packaging:

(a) The name of the pharmacy;

(b) The name and age of the patient (the name of the animal's owner and the age of the animal) where these particulars are shown on the prescription;

(c) The name or composition, and the quantity, of the medicament, except in the case of medicaments in respect of which the medical practitioner has expressly indicated on the prescription that the composition shall not be entered on the signature;

(d)[l] Directions for use: If the prescription bears the words "Dosage notified to patient" or similar wording (see section 4, para. 5), the words "To be used as indicated by the medical practitioner (veterinary surgeon, dental surgeon)" shall be entered.

Medicaments for external application shall be marked: "For external application" or "External" if this is not already clearly apparent from the text on the packaging. These requirements shall not apply where medicaments are prescribed without directions for use by a hospital or the like or for use in the practice of the issuer of the prescription;

(e)[m] The occupation and name of the person issuing the requisition. This shall not be necessary where medicaments are prescribed without directions for use by a hospital or the like;

(f)[m] The date of filling of the prescription and the signature of the dispenser. The signature of the dispenser shall not be necessary where the medicament is prescribed without directions for use by a hospital or the like.

3.[n] (a) Medicaments with sediment or medicaments in which precipitation or separation into two phases may occur shall when issued be marked: "Shake".

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l/ Regulation of 28 April 1972.

m/ Regulation of 15 October 1974.

n/ Regulation of 15 March 1976, to enter into force on 1 April 1976.

(b) Tablets to be chewed shall when issued be marked "To be chewed".

Tablets to be sucked shall when issued be marked: "Tablets to be sucked. Should not be chewed".

(c) When injectable fluids containing only an active substance are issued their strength shall be indicated in mg/ml.

When injectable fluids and infusions for human use are issued the mode of application shall be specified;

(d) Medicaments for animals shall when issued be marked: "Medicament for animals".

4. When a signature is applied to preparations in an original package, the signature of the pharmacy shall so far as possible be applied to the inner packaging. The name of the preparation must always be visible.

5. The signature shall be marked with the poison marking (death's head or "Poison" printed in white on a black or blue ground) when the following are issued:

(a) Medicaments of group A;

(b) Medicaments whose only or principal constituent is a barbituric acid derivative;

(c) n/ (cancelled).

(d) f/ A medicament prescribed in an "ad hoc" preparation for the individual patient, when the stated single dose or day's dose is greater than the stipulated maximum dose; cf. annex II.

Where h/ delivered to a hospital or the like, medicaments as referred to under (a) shall bear, in addition to the poison marking, the words: "In poisons locker" printed in white on a black or blue ground.

6. f/ Each individual portion shall be provided with the poisons marking when an "ad hoc" medicament is issued divided into portions each of which exceeds the stipulated maximum single dose for adults, cf. annex II.

7. Medicaments in tablet form or the like (solution-tablets, pessaries, etc.) not intended to be taken "per os" shall when issued bear a signature with the following text: "Caution. Not to be eaten".

8. Medicaments having a specified maximum shelf-life shall when issued display the following text: "Will keep until (date)", or the like.

9. Preparations which are to be kept cold shall be marked: "To be stored cold, but without freezing".

10. o/ Prescription medicaments shall when issued be marked with the following warning text: "To be kept out of reach of children".

The duty to affix the marking shall not apply where the medicament is prescribed for a hospital or the like or for use in the practice of the issuer of the prescription.

Section 14. Special provisions regarding signature and issue

1. Special provisions regarding the signature which are included under entries in the pharmacopoeia relating to individual substances or preparations shall apply in addition to the present requirements. The special provisions of the pharmacopoeia shall also apply where analogous substances or preparations are issued.

2. Sublimates for external application in an unmixed form or mixed with other substances may be prescribed and issued in a form not ready for use. The dyestuff acid violet shall be added to the substance or mixture (0.6 mg per gramme of mixture), and the substance or mixture may be issued only in portions containing not more than 1 g of sublimate.

The provisions of section 13, paragraph 6, requiring each portion of the medicament to be provided with the poison marking shall not apply to solution-tablets of sublimate. The packaging for a medicament containing a sublimate shall when issued bear the poison marking. Preparations intended to be dissolved, diluted or the like shall in addition bear the following text:

> "May not be dissolved or stored in or decanted into bottles, flasks, or other recipients which are normally used for beverages".

Where sublimates intended to be dissolved or diluted are issued, a sufficient number of "poison" markings on gummed paper shall be issued at the same time. The provisions in this paragraph concerning sublimates shall also apply to other mecurial compounds for disinfectant purposes.

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5. Where procaine 3/ or tetracaine is prescribed in the form of a solution under a name other than that used in the pharmacopoeia, the signature on the medicament shall when issued bear, in addition to that name, the pharmacopoeial name in parentheses.

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o/ Regulation of 30 December 1967.

3/ Note by the Secretariat: International non-proprietary names of drugs are underlined.

6.[p/] Eye-drops shall not be issued in quantities exceeding 20 ml per unit packaging.

7.[o/] Where fluid medicaments for oral use are issued against a prescription in which the dose is specified in tablespoonfuls, dessertspoonfuls or teaspoonfuls (or in ml) they shall be accompanied by a medicine-measure meeting the requirements of the pharmacopoeia in the matters of material and of instrument tolerance.

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IV. "OVER-THE-COUNTER" ISSUE OF MEDICAMENTS

Section 15. Non-prescription medicaments

The following may be issued "over-the-counter":

1. Substances, [b/] drugs and preparations which are listed in schedules valid at the time but are not marked with one of the letters A, B, C and D, and compounds and the like prepared from the (special provisions, see section 18).

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2. Prescription medicaments to the extent that they have been specifically exempted..

Section 16. Misuse

Medicaments and other goods which because of their content of ether, alcohol or other substances may be used as intoxicants shall not be issued in cases where it is likely that they will be misused..

Section 17. General provisions concerning the signature

1.[l/] When sold "across-the-counter", medicaments for external application shall bear a signature reading: "For external use" or "External", unless this is already clearly apparent from the text on the packaging.

2. When issued, a medicament other than a patent medicine shall bear the name of the pharmacy and the Norwegian name of the medicament in accordance with an approved or common nomenclature. The name shall not give misleading information concerning the action or quality of the medicament. If the medicament has no Norwegian name, or if the Norwegian name does not provide adequate particulars to enable a corresponding medicament to be issued later by another pharmacy, further particulars, such as an unambiguous Latin designation, or the composition, shall be entered on the signature.

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p/ Regulations of 21 March 1967 and 27 March 1969.

Section 18. Special provisions concerning the signature

When the medicaments described below are issued "across-the-counter" the following rules shall apply:

1. Medicaments containing substances as named below may be issued in an unmixed form or mixed with other solid substances, only in a dosed form. Each dose shall contain not more than:

caffeine and caffeine compounds ..... 0.1 g;

acetylsalicylic acid, phenazone,
phenazone salicylate and salicylamide ..... 1 g.

2. Ether, Hoffmann's anodyne, and camphor essence may be issued, in an unmixed form or in the form of mixtures of these substances, only in flasks of not more than 25 ml at a time, with the signature:

"For medicinal use. 10-20 drops at a time". Signatures for ether shall in addition bear the inscription: "Inflammable".

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5. The provision of section 13, paragraphs 7, 8 and 9, shall also apply to "over-the-counter" sales.

6. When medicaments which according to the "Regulations concerning substances dangerous to health" are to be regarded as dangerous to health are sold "over-the-counter", the provisions in the said Regulations shall apply.

7. o/ Medicaments containing salts of iron, acetysalicylic acid, or compounds of the latter, shall be marked with the following warning text:

"To be kept out of reach of children".

8. n/ Herbs and mixtures of herbs shall be marked with the following text:

"The medicinal action of this herbal preparation has not been assessed by the public medicaments-control authority, as is done in the case of approved medicaments. A necessary examination and treatment by a medical practitioner must not be postponed or be replaced by a course of herbal treatment otherwise than after consultation with the medical practitioner".

Section 19. Exceptions to the prescription requirement

The substances and preparations named below for which a prescription is required may be issued without production of a prescription to the extent and subject to the conditions indicated; cf. also the Patent Medicines Schedule.

Substances or preparations	Form, strength and quantity of medicament	Special provisions, signature, etc.
Benzocaine	Suspensio benzocaini composita NAF 64, maximum 10 ml. r/	
Emetic herb	Extract. Up to ½% strength. Emeticum ipecacuanhae NAF 64, maximum 60 ml. p/	Directions for use to be entered. Approved directions for use to be entered. 3/
Diphenhydramine	Mixed with caffeine as tablets. Up to 50 mg per tablet, maximum 10 tablets.	Signature: "Tablets against travel sickness. Must not be used by drivers of motor vehicles. Adults: 1 tablet up to four times a day. Children: 1/4-½ tablet up to four times a day".
Ephedrine	Up to 1% in ephedrine nose-drops, maximum 10 ml.	Signature: "Nose-drops. Nursing infants: 1 drop; children over 1 year: 1-3 drops; adults: 3-4 drops in each nostril up to four times a day. Used for up to one week at a time. Where used simultaneously with cough syrup containing ephedrine the medical practitioner must be consulted".
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Chlorbutol b/	Solutions, up to 0.5% as preservatives.	
Chloroform	Medicaments for external application, up to 33 3/4%	Signature: "Caution. Poisonous. For external application".

r/ Regulation of 30 September 1966.

Substances or preparations	Form, strength and quantity of medicament	Special provisions, signature, etc.
Codeine phosphate	Mixed with acetylsalicylic acid as tablets. Up to 10 mg per tablet, maximum 20 tablets.	Tablets to bear the signature: "For adults: 1 tablet up to four times a day. Must not be given to children. Prolonged use may cause harmful effects".
.....		
Lidocaine ro/	Ointments up to 5% strength, maximum 20 g. Liniments up to 3% strength, maximum 100 ml. Dosed medicaments up to 60 mg per dose, maximum 10 pieces. Ear-drops up to 0.5% strength, maximum 10 ml.	
.....		
Oxeladin citrate m/	Mixtura oxeladini citratis 250 ml.	Directions for use to be entered.

The preparation is to be marked "D" in the medicinal schedule.

.....

ANNEX I[s/]

ANNEX II[f/]

Maximum doses

The maximum doses listed below apply to substances included in medicaments prepared "ad hoc".

Where a maximum dose is not indicated as applicable to a particular mode of use it shall apply to all modes of use other than external application.

Where, for a particular substance, maximum doses are indicated for both oral and other than oral modes of use, the maximum oral dose shall also apply to other modes of use which are not specified, other however than parenteral and external application.

Where the dose of a medicament is defined in tablespoonfuls, dessertspoonfuls or teaspoonfuls, the following quantities shall be used as a basis for determining the size of the prescribed dose:

Tablespoonful : 15 ml;

Dessertspoonful : 10 ml;

Teaspoonful : 5 ml.

For aqueous and oily solutions or suspensions, 1 ml is taken to be equivalent to 1 g.

Where the dosage of a medicament is defined in drops, the size of the dose shall be computed on the basis of the number of drops per gramme of the medicament as produced with an ordinary dropper.

The maximum doses indicated in the following table are valid for adults only. Equivalent doses for children are calculated by means of the following table:

Age of child			Relationship of maximum child's dose to maximum adult dose
New-born	to	3 months	1/20
3 months	to	9 "	1/10
9 months	to	2 years	1/7
2 years	to	4 "	1/5
4 "	to	6 "	1/4
6 "	to	10 "	1/3
10 "	to	12 "	1/2

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s/ Annex I deleted through Regulation of 16 September 1974.

Maximum doses for adults

	Single dose	Day's dose
.....		
Aethylmorphini chloridum	50	150 mg
Amphetamini sulfas	20	40 mg
p.e.***/	10	20 mg
Apomorphini chloridum	20 mg	40 mg
.....		
Atropini sulfas	2 mg	4 mg
.....		
Cocaini chloridum	30 mg	60 mg
Cocaini nitras	30 mg	60 mg
Cocainum	30 mg	60 mg
Codeini chloridum	50 mg	150 mg
Codeini phosphas	50 mg	150 mg
Codeinum	40 mg	120 mg
.....		
Dexamphetamini sulfas	10 mg	20 mg
p.e.	5 mg	10 mg
.....		
Diluendum glyceryli nitratis 10%	10 mg	100 mg
Ephedrini chloridum	50 mg	150 mg
Ephedrini sulfas	50 mg	150 mg
Ephedrinum	40 mg	120 mg
Erythryli nitras	30 mg	90 mg
.....		
Extractum belladonnae	0.1 g	0.2 g
Extractum nucis vomicae	50 mg	100 mg
Folium digitalis lanatae	0.3 g	0.3 g
Folium digitalis standardisatum	0.2 g	0.2 g

***/ p.e. = parenteral(ly)

	Single dose	Day's dose
Lanatosidum C	1.2 mg	1.2 mg
p.e.	0.8 mg	0.8 mg
Levorphanoli tartras	6 mg	18 mg
Metaoxedrini chloridum	0.25 g	
i.m.****/	10 mg	
s.c., i.v.	1 mg	
Metaraminoli bitartras		
i.m.	15 mg	30 mg
s.c., i.v.	5 mg	10 mg
Methadoni chloridum	15 mg	45 mg
Methamphetamini chloridum	20 mg	40 mg
p.e.	10 mg	20 mg
Methoxamini chloridum		
i.m.	20 mg	60 mg
i.v.	10 mg	30 mg
Methylatropini bromidum	2 mg	4 mg
p.e.	1 mg	2 mg
Methylatropini nitras	2 mg	4 mg
p.e.	1 mg	2 mg
Methylphenidati chloridum	10 mg	30 mg
Metoponi chloridum	6 mg	18 mg
Morphini chloridum	20 mg	60 mg
Morphini sulfas	20 mg	60 mg
Neostigmini bromidum	30 mg	90 mg
p.e.	1 mg	3 mg
Noradrenalini bitartras		
p.e.	0.2 mg	
Noradrenalinum		
p.e.	0.1 mg	
Opium pulveratum	0.2 g	0.6 g
Oxedrini tartras	0.15 g	0.6 g

****/ i.m. = intramuscular(ly)

	Single dose	Day's dose
Oxiconi chloridum	20 mg	60 mg
Papaverini chloridum	0.2 g	0.6 g
Pentymalum	0.3 g	0.3 g
Pethidini chloridum	0.2 g	0.6 g
Phenemalum	0.3 g	0.3 g
Phenmetralini chloridum	30 mg	90 mg
Pilocarpini chloridum	20 mg	40 mg
p.e.	10 mg	20 mg
Pipradroli chloridum	10 mg	40 mg
Scopolamini bromidum	2 mg	4 mg
Tetracaini chloridum	20 mg	20 mg
Tetraponum	20 mg	60 mg
Thebaconi chloridum	10 mg	30 mg

E/NL.1976/144

Ministry of Social Affairs

Oslo, 26 April 1976

RESTRICTIONS ON THE DISPENSING OF METHADONE

AMENDMENT TO THE REGULATIONS OF 19 FEBRUARY 1965[4/] ON THE PRESCRIBING OF DRUGS AND THEIR DISPENSING BY PHARMACIES

Considering section 5 of the Law of 29 April 1927 concerning the rights and duties of medical practitioners; section 5 of the Law of 29 April 1927 concerning the rights and duties of dental surgeons; section 8 of the Law of 10 December 1948 concerning veterinarians and section 32 of the Law of 21 June 1963 concerning the operation of pharmacies; sections 20 and 21 of the Law of 20 June 1964 1/ concerning medicaments and poisons; and having regard to part II of the Royal Decree of 19 February 1965, the Ministry of Social Affairs hereby orders that the following addition shall be made to section 14 of the Regulations of the same date concerning the prescribing of drugs and their dispensing by pharmacies. Special provisions on signing for and dispensing drugs:

4/ Note by the Secretariat: E/NL.1976/143 (up-dated version of 1976).

New sub-section 10

Pharmacies may dispense drugs containing methadone for medical use by human beings only in the form of approved pharmaceutical preparations.

The amendment shall enter into force on 1 July of this year.

EXPLANATORY NOTE:

In view of the increase in the prescribing of methadone for young drug abusers, the Director of Public Health sent out a notice on 19 July 1974 to all medical practitioners, emphasizing that to prescribe methadone for drug users as a normal practice is not regarded as professionally responsible behaviour.

Investigations have shown that the circular has not had the desired effect, since the bulk of methadone prescribing is for young people.

In order to restrict the use of methadone, the Social Ministry of Affairs has ruled that methadone preparations for medicinal use by human beings may be dispensed by pharmacies only in the form of approved pharmaceutical preparations. At the request of the Director of Public Health, the Board on Special Preparations has laid down further conditions for the registration of preparations containing methadone, stipulating that preparations for medical use by human beings can be dispensed only for use in hospitals.

The Director of Public Health trusts that the restriction on the right to prescribe methadone will not lead to the increased use of other drugs in Group A. Reference is also made to his directives of August 1974 on the prescribing of dependence-producing drugs.

By order

(Signed.) Torbjørn Mork

(Signed.) B. Jøldal