UNITED NATIONS

E/NL. 1974/24-27
2 July 1975
ENGLISH ONLY

# LAWS AND REGULATIONS

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

## SWEDEN

Communicated by the Government of Sweden

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

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Medicinalväsendet No. 100-103, 1965 E/NL.1974/24

Board of Health

### NOTICE CONCERNING THE PRESCRIPTION OF MEDICAMENTS, THEIR DISPENSING FROM PHARMACIES, ETC.

(PRESCRIPTIONS NOTICE)

15 November 1965

Under article 5 of the Medicaments Order, the Board of Health is competent to issue provisions concerning the marking, dispensing and prescription of medicaments. Similarly under article 3, paragraph 3, of the General Instructions to Physicians it is the duty of every physician, on prescribing a medicament, to comply with the provisions laid down on the subject by the Board of Health. Therefore the Board of Health hereby orders as follows.

### INTRODUCTORY PROVISIONS

Article 1

The term "medicament" means any commodity to which the Medicaments Order applies.

Article 2

The following medicaments may, except in the circumstances specified in article 14, be dispensed from a pharmacy only against a prescription:

1. A registered patent medicine in so far as the Board of Health has so ordered;

2. Any other medicament containing a substance listed in a special schedule laid down by the Board of Health (schedule I to the Prescriptions Notice);

3. Any other medicament containing a poison or more than 10 per cent by weight of ethanol and not exempted from the prescription requirement under a special schedule laid down by the Board of Health (schedule II to the Prescriptions Notice); and

4. A bacteriological preparation.

A medicament to which this article applies shall hereinafter be referred to as a "medicament subject to prescription".

Article 3

The term "prescription" (recept) means a prescription (ordination) or order issued in writing or by telephone by a person competent to practise medicine, dentistry or veterinary surgery. An order for a medicament not subject to prescription shall however be regarded as a prescription only if it includes directions for the use of the medicament.

ORDERING BY PRESCRIPTION

Article 4

1. An order by prescription shall as a rule be made in writing. Ordering by telephone (telephoned prescription) should, because of the risk of error, be limited to cases in which it is necessary.

2. A prescription is valid for a period of one year from its issue.

3. Narcotic drugs or other medicaments which present a risk of dependence shall be prescribed with the greatest caution. A narcotic drug shall not be prescribed for a person unknown to the prescriber unless the identity of the person concerned is reliably substantiated. A narcotic drug may be prescribed by telephone only in case of emergency and in separate doses in the form of powder, tablets, suppositories or other preparations for rectal administration, and the quantity prescribed on any one occasion shall not exceed five such doses.

Article 5

A written prescription shall be made out in the following manner:

1. A prescription shall state the name, profession, address and telephone number of the person making out the prescription or, where applicable, the name, address and telephone number of the medical institution concerned. As a rule a printed form shall be used for this purpose.

A prescription form on which the name of the medicament is printed shall not be used for prescribing a narcotic drug.

Only the obverse side of a prescription form may be used. A prescription for a medicament which consists of a narcotic drug or technical spirit shall not include any other medicament.

Prescription forms shall be kept in such a manner that they are not accessible to any unauthorized person.

2. A prescription shall be worded clearly, without any such abbreviations or alterations as may raise doubt concerning its correct interpretation.

3. On making out a prescription for medicaments for an individual consumer, a physician or dentist shall, unless there is some reason to the contrary, enter the name and date of birth of the person for whom the medicament is intended. A veterinary surgeon shall enter the name of the animal's owner and the species of animal. If a narcotic drug is prescribed, the address of the patient or of the animal's owner shall also be entered.

If the medicament is intended for a medical institution or similar consumer or for an industrial medical officer's consulting room, a district nurse's practice or the like, the aforementioned particulars shall be replaced by the name of the institution or the name and address of the enterprise by which, or the person by whom, the medicament is to be held.

4. The nature, strength and quantity of the prescribed medicament shall be clearly stated. In the case of a narcotic drug, the quantity shall be stated both in figures and in words. When prescribing a patent medicine, the prescriber shall adapt the quantity to the packages found in the trade.

5. A prescription for a medicament for a medical institution shall, if the medicament is subject to prescription and intended for internal use, a/ contain particulars of the dosage unless general agreement on the normal dosage is reached between the senior medical officer concerned and the pharmacy. In the case of a medicament intended for a use other than oral administration, particulars shall be given of the method of use unless this is clear from the name of the medicament.

When making out a prescription for another consumer, the prescriber shall give the necessary directions for the use of the medicament. In the case of a medicament subject to prescription which is intended for internal use, the directions shall include a provision concerning dosage.

Where the medicament ordered is intended for the prescriber's own use or practice, the direction just mentioned shall be replaced by, e.g., the words "ad usum proprium" or "In manu medici".

A physician or dentist shall not deliver to a person under his treatment a medicament in a quantity larger than that needed for the treatment of that person until he can obtain the medicament from a pharmacy in the usual manner. The same shall apply "mutatis mutandis" to the delivery of a medicament by a veterinary surgeon to the owner of an animal.

6. Where a medicament which is subject to prescription and for which the pharmacopoeia specifies a maximum dose, or which contains a substance having a specified maximum dose, is prescribed for human internal use in a dose larger than the maximum, the prescriber shall add the word "sic" unless the prescription orders for an adult person a single dose of a patent medicine that is divided into doses.

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a/ The expressions "for internal use" and "for external use" have in this Notice the same meaning as in the current pharmacopoeia; but for the purpose considered here, ointments and eye lotions shall be treated as medicaments for external use.

7. Where special promptness is required in dispensing a prescription, the prescriber shall so indicate by adding the word "Cito".

8. A prescription shall bear the date on which it was issued and shall be signed by the prescriber "manu propria". If a prescription form is used on which the prescriber's name is not printed, his name shall be added in block capitals, preferably stamped, below his signature. An unqualified prescriber shall, below his signature, either add the words "Directed by ..... to serve on the above date as .....", or state his official position and place of employment.

9. The prescriber may, by endorsing the form, prescribe repeated dispensing (iteration) of a medicament which does not consist of a narcotic drug or technical spirit. Such an endorsement shall not cover more than three iterations and shall, if this is deemed appropriate, require that the medicament shall not be dispensed again until a certain minimum time has elapsed. The number of iterations shall be stated in words. The iteration of free medicaments which are referred to in the Order of 4 June 1954 (No. 519) concerning Medicaments Free of Charge or at Reduced Prices shall be governed by the special regulations laid down on the subject.

Article 6

1. A prescriber telephoning a prescription shall:

(a) State his name and, unless these particulars are known at the pharmacy, his profession, address and telephone number or, where applicable, the name, address and telephone number of the medical institution concerned;

(b) Where applicable, comply with the provisions of article 5, paragraphs 3-6, concerning written prescription, and where possible state the address of the patient (or of the owner of the animal) even when prescribing a medicament other than a narcotic drug.

The dispensing of a telephoned prescription shall not be repeated.

2. A telephoned prescription shall be received by a pharmacist, who shall write down all the particulars on the appropriate form directly at the telephone and read back his notes at once for approval by the prescriber.

The pharmacist shall confirm the receipt of the prescription by entering on the form his name and the year and day of receipt. If there is reason to suspect that the prescriber is not the person he declares himself to be, the caller's identity shall be checked. The check made shall be certified by the pharmacist by endorsement on the form. In the case of a narcotic drug, the check may be omitted only if the prescriber's identity is obvious.

THE DISPENSING OF MEDICAMENTS IN GENERAL

Article 7

Medicaments shall be prepared and dispensed with special exactitude in order to obviate confusion and mistake. In addition all possible care shall be taken to ensure that the medicaments dispensed are free from visible defects and deficiencies.

Article 8

1. A part of a patent medicine shall not be dispensed. There is, however, no reason why a package of a patent medicine should not be broken open at a pharmacy in

order that the contents may be used as an ingredient of a medicament prepared "ad hoc", provided that the Board of Health, on application by the manufacturer of the patent medicine, gives permission therefor. b/

2. A package of a patent medicine shall not be dispensed if it has been withdrawn by the manufacturer or if its retention is restricted to such a date that there is reason to suppose that the entire quantity will not, in normal use, be consumed by that date.

Article 9

1. Special regulations have been laid down concerning the marking of patent medicines.

2. Other medicaments shall bear a label showing first the name of the pharmacy and then the nature and composition of the medicament according to its name in the current pharmacopoeia, or its name in another handbook current at pharmacies, accompanied by particulars of the source of the name, or, if no such name exists, a complete statement of its composition and content of ingredients; however, an ingredient which is indicated in the manner just described or which consists of a patent medicine need not be further specified. The label shall be white if the medicament is intended for internal use and red if it is intended for external use. The label on a medicament ready for injection shall be white with a red stripe running diagonally upwards from the bottom left-hand corner.

Furthermore the marking shall include:

(a) The words "To be kept out of children's reach" unless the medicament is intended for a medical institution or similar consumer;

(b) The words "For external use" if the medicament is intended for such use;

(c) The words "Shake the bottle" if the medicament is separated or may settle out into phases;

(d) The words "For injection" if the medicament is ready to be injected into body tissues or blood-vessels;

(e) Directions on the proper method of storage in the case of a medicament that is sensitive to heat, damp or the like; and

(f) Such other directions as may be attached to the medicament in question pursuant to the current pharmacopoeia or a provision issued by the Board of Health.

THE DISPENSING OF MEDICAMENTS ON PRESCRIPTION

Article 10

1. A medicament ordered by prescription shall be prepared for dispensing by a pharmacist.

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b/ Such permission shall be granted by inclusion of the price for such use in the official schedule of medicament prices.

2. The pharmacist concerned shall be under a duty to verify that the provisions concerning the prescription of medicaments have been complied with. In case of doubt concerning the correct interpretation of a prescription, or where a prescription is unclear, incomplete or obviously incorrect, clarification or correction shall be obtained from the prescriber. If there is reason to suppose that a prescription is forged, the prescribed medicament shall not be dispensed until the stated prescriber has confirmed on inquiry that the prescription is genuine.

3. A prescription may be dispensed again only in accordance with the directions given by the prescriber.

4. Without the consent of the prescriber, no departure shall be made from the terms of a prescription save in virtue of a provision of the current pharmacopoeia or other enactment or as may be required on technical grounds, and where the effect of the medicament is not altered thereby. Nothing in this provision shall confer a right to dispense more than the prescribed quantity, including iterations, without the prescriber's consent. Where a patent medicine is prescribed in a quantity substantially disproportionate to the available packages, the prescriber shall be given an opportunity for correction. If he cannot be found, the next smaller package may be dispensed.

Where a medicament or substance with a protected name is prescribed, it shall not be replaced by another.

5. A departure or correction as described above shall be recorded on the prescription form and confirmed by the pharmacist with his signum.

Article 11

1. Every package of a medicament dispensed on prescription shall bear, in addition to the marking specified in article 9, a label showing:

(a) Directions by the prescriber for the use of the medicament;

(b) The prescriber's name;

(c) The name of the pharmacy; and

(d) The year and day of dispensing.

The label on a medicament intended for human use shall also reproduce the prescriber's information concerning the person's name and date of birth or the name of the medical institution or the like for which the prescription is issued.

A label for a medicament prescribed by a veterinary surgeon shall bear the words "For an animal" and the prescriber's information on the species of animal for which the medicament is intended.

A label on a medicament prescribed by a dentist shall bear the words "For dental treatment".

With regard to the colour of the label, the provisions of article 9, paragraph 2, shall also apply to patent medicines.

2. The pharmacist preparing a medicament shall affix his signum to the label and in so doing, if the medicament is a patent medicine, shall ensure so far as possible that the marking affixed by the manufacturer is not covered. If the name

of the medicament or information, directions or cautions important for the correct use of the medicament are covered or rendered less conspicuous, the corresponding text shall be reproduced on the pharmacy label or otherwise.

3. Where a medicament prescribed for an individual consumer is dispensed in two or more packages, each package shall also bear a clear indication of that fact.

4. Where a medicament intended for injection and ordered for a medical institution or similar consumer, or a medicament subject to prescription and intended for ingestion or rectal application, is dispensed, the label shall also give particulars of the principal active ingredient or ingredients in ordinary dosage, unless this is clear from the name of the medicament or from other information on the package.

Article 12

1. A medicament to be used in the form of drops shall be dispensed in a package which is supplied with a suitable dropper.

2. A medicament which is prescribed for an individual consumer and for which the dosage is stated in tablespoons, dessert spoons or teaspoons shall be accompanied on dispensing by a medicine measure, e.g. in the form of a dosing spoon.

Article 13

1. Whenever a prescription is dispensed it shall be stamped with the name of the pharmacy and the day and year. The pharmacist preparing the medicament shall affix his signum to the stamp. Where a prescription includes more than one medicament and these are not dispensed at the same time, or where in a particular case less than the full prescribed quantity of a medicament is dispensed, the pharmacist shall indicate on the stamp which medicament or what quantity has been dispensed.

2. Where, in the case of a medicament prepared "ad hoc", the prescriber has left it to the pharmacist to determine the addition of an excipient necessary for the production of the medicament, the nature and quantity thereof shall be stated on the prescription.

3. A note of the price of each medicament shall be made on the prescription.

4. The form recording a telephoned prescription or any other prescription for a narcotic drug or technical spirit shall be kept at the pharmacy.

THE ORDERING AND DISPENSING OF MEDICAMENTS WITHOUT A PRESCRIPTION

Article 14

A medicament subject to prescription may be dispensed from a pharmacy without a prescription at the order of:

(a) A pharmacist who is in charge of the central store of medicaments at a medical institution, unless the medicament consists of a narcotic drug or is subject to prescription because of its ethanol content;

(b) A shipmaster or chief pilot in the case of a ship's pharmacy or the Pilotage Service medical supplies, in accordance with the applicable provisions;

(c) The director of a scientific or similar institution at a university or other higher educational establishment or of an analytical laboratory, a research institute or the like that is owned by or receives support from the State or a commune, but only for purposes other than medical treatment.

Article 15

A medicament subject to prescription that is ordered by a person referred to in article 14 shall be prepared for dispensing by a pharmacist. For the purpose of setting the price of the medicament, such an order shall be regarded as equivalent to a prescription.

Article 16

1. An order made by the pharmacist in charge of the central store at a medical institution shall as a rule be in writing and bear the name of the medical institution, the date of the order and the pharmacist's signature. If the medicament is to be prepared by the pharmacy for issue to a branch store, the particulars given shall also include the name of the physician who has requisitioned the medicament from the central store and such provisions and directions as he may lay down or as may be otherwise attached to the medicament on dispensing from the central store. If the order is placed by telephone it shall be confirmed by a written requisition as soon as possible.

2. When a medicament is dispensed on an order of the kind referred to in paragraph 1, every package shall bear, in addition to the marking required by article 9, a label showing the name of the pharmacy and the date of dispensing. The pharmacist preparing a medicament subject to prescription shall affix his signum to the label thereof.

When a medicament is prepared for issue to a branch store, the procedure for marking shall be that specified for the dispensing of medicaments on prescription.

Article 17

An order made by a shipmaster or chief pilot shall be governed by the special regulations laid down on the subject.

Article 18

An order made for a medicament subject to prescription by the director of a scientific institution, analytical laboratory or other establishment referred to in article 14, sub-paragraph (c), shall be in writing and bear the name of the institution or laboratory and the purpose for which the medicament is to be used, and shall be signed by the director.

On dispensing, every package shall bear, in addition to the marking required by article 9, the name of the pharmacy, the date of dispensing and the signum of the pharmacist responsible for the preparation.

Article 19

An order of the kind referred to in articles 16-18 shall be kept at the pharmacy.

Article 20

When a medicament is dispensed otherwise than on prescription or than on an order of the kind referred to in article 14 - i.e., is purchased direct - the following provisions shall apply in addition to those laid down previously concerning the dispensing of medicaments in general.

1. If the order gives particulars of the use of the medicament, account shall be taken, with regard to the marking of the medicament, of the applicable parts of the pro isions laid down concerning medicaments dispensed on prescription; but the purchaser's name shall not be entered on the label.

2. A medicament for external use which contains a dangerous substance in such a quantity that the medicament is comparable to a commodity dangerous to health shall bear a warning notice of the kind required upon transfer of the dangerous substance in question.

3. A medicament dispensed to a medical institution or similar consumer shall bear the date of dispensing.

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This Notice shall enter into force on 1 March 1966; for the purposes of a prescription issued before that date, the provisions referred to in article 10, paragraph 2, concerning the prescription of medicaments shall be the provisions in force on the date of issue of the prescription.

The following are hereby rescinded:

The Board of Health Notice of 4 December 1919 (Svensk författningssamling (SFS) No. 771) concerning the telephoning of prescriptions to a pharmaceutical establishment;

The Board of Health Notice of 11 February 1922 (SFS No. 73) concerning the dispensing of certain toxic medicaments from pharmacies on the requisition of a medical auxiliary, and the conditions for the use thereof by a medical auxiliary;

The Board of Health Circular of 27 March 1924 (Medicinalväsendets författningssamling (MF) No. 30) concerning the sale from pharmaceutical establishments of medicaments which are offered for sale in the original packages or as so-called patent medicines;

The Board of Health Notice of 16 December 1940 (MF No. 118) concerning the dispensing of patent medicines from pharmaceutical establishments;

The Board of Health Circular of 3 February 1941 (MF No. 13) concerning the communication to the Board of Health of information on patent medicines which a manufacturer intends to place on the market also in bulk, etc.

The Board of Health Notice of 20 May 1947 (MF No. 75) regarding the prescription and supply of medicaments by pharmacies etc. (Notice on Dispensing); 1/

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1/ Note by the Secretariat: E/NL.1948/34.

The Board of Health Notice of 13 October 1953 (MF 1954 No. 10) concerning the dispensing from pharmacies of certain medicaments containing alcohol;

The Board of Health Notice of 6 December 1960 (MF No. 108) concerning the requirement of a prescription for certain medicaments;

The Board of Health Notice of 27 February 1962 (MF No. 20) 2/ on the prescribing of narcotic drugs and on their dispensing by pharmacies, etc.

Where reference is made in a previous notice or otherwise to a provision which is replaced by a provision of this Notice, the latter provision shall be applied in lieu thereof.

Engel, Rahm, Linder, Krook, Liljestrand (The Pharmaceutical Office)

Board of Health E/NL.1974/25

CIRCULAR CONCERNING THE REQUIREMENT OF A PRESCRIPTION FOR CERTAIN REGISTERED PATENT MEDICINES

7 December 1965

Article 2 of the Board of Health Notice of 15 November 1965 (MF No. 100) 3/ concerning the prescription of medicaments, their dispensing from pharmacies, etc. (the Prescriptions Notice) provides that a registered patent medicine shall be subject to prescription in so far as the Board has so ordered.

Pursuant thereto, the Board of Health hereby announces that the Board's decision subjecting such a patent medicine to prescription will be signified by printing the sign ℞ against the name of the patent medicine in the publication Apotekens specialitetsregister.

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This Circular shall take effect on 1 March 1966.

Rahm, Linder, Liljestrand (The Pharmaceutical Office)

Medicinalväsendets författningssamling MF 1972: 28 E/NL.1974/26

Board of Social Welfare

CIRCULAR ON THE PRESCRIPTION OF NARCOTIC DRUGS IN CERTAIN CASES

1 June 1972

Pursuant to article 5 of the Medicaments Order, the Board of Social Welfare issues provisions concerning the prescription of medicaments. Similarly under

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2/ Note by the Secretariat: E/NL.1964/25.

3/ Note by the Secretariat: E/NL.1974/24.

article 3, paragraph 3, of the General Instructions to Physicians it is the duty of every physician, on prescribing a medicament, to pay attention to what the Social Welfare Board has laid down on the subject. The Social Welfare Board has laid down in the Prescriptions Notice (MF 1965: 100) 3/ a rule that narcotic drugs or other medicaments which present a risk of dependence shall be prescribed with the greatest caution.

From the experience gained so far in the treatment of persons abusing opiates, this rule may present difficulties of interpretation in certain cases. The Social Welfare Board has therefore decided to issue the following provisions for the guidance of physicians who treat the condition in question.

1. Provided that good and frequent contact is maintained with the patient, opium, opium alkaloids or morphine substitutes may be prescribed for out-patients in the following cases:

(a) For a short time while the patient is awaiting admission to an institution for withdrawal treatment in order to rid him of abstinence symptoms of the more troublesome kind;

(b) As a stage in oral methadone treatment by the Dole-Nyswander method. In view of the difficulties associated with this method of methadone treatment, it is assumed for the time being that such treatment begins in the Research Clinic at Ullerakers Hospital, Uppsala, where experience has already been gained with this method of treatment and where cases from all over the country can gain admission on referral by a specialist. After consultation with the Social Welfare Board,however, such treatment may be introduced at another hospital;

(c) In inveterate cases. This applies to a small number of patients for whom narcotic drugs are prescribed for self-administration. This should be allowed in cases where any other treatment is deemed purposeless. In new cases in which such treatment is contemplated, methadone treatment by the Dole-Nyswander method should be tried first.

2. The prescription of narcotic drugs for self-administration should be avoided, e.g. by arranging for the drug to be taken in the physician's consulting room or at the pharmacy. In some instances this may prove impossible. If so, the prescription should be made valid for dispensing only at a particular pharmacy and within a specified time.

3. Drugs shall not be prescribed for parental administration. In isolated cases this may, however, be allowed after consultation in accordance with paragraph 5 below.

4. All cases in which opiates are prescribed for out-patients on indications of drug addiction shall be reported to the Board of Social Welfare.

5. Before treatment is begun under paragraph 1 (c), the Board of Social Welfare shall be consulted.

Rexed, Hedengren, Alsén, Liljestrand, Langton, Nordström, Leche, Ording, Krook, Kihlbom.

Medicinalväsendets författningssamling MF 1972: 33 E/NL.1974/27

Board of Social Welfare

NOTICE AMENDING THE PRESCRIPTIONS NOTICE

7 June 1972

Pursuant to article 5 of the Medicaments Order, the Board of Social Welfare hereby decrees that article 4, paragraph 3, and article 5, paragraphs 1, 3 and 9, of the Board of Health Notice of 15 November 1965 (MF No. 100) 3/ concerning the prescription and dispensing of medicaments from pharmacies etc. (the Prescriptions Notice) shall be amended to read as follows:

Article 4

3. Narcotic drugs or ..... such doses.

The restriction with regard to the form of preparation and the quantity prescribed shall not apply to substances which are included in Schedules IV and V of the Board of Social Welfare Notice giving Schedules of Narcotic Drugs.

Article 5

1. A prescription shall ..... a narcotic drug.

Only the obverse side of the prescription form may be used. A prescription for a medicament which consists either of a substance referred to in Schedule II of the Board of Social Welfare Notice giving Schedules of Narcotic Drugs or of technical spirits shall not include any other medicament.

Prescription forms shall be kept in such a manner that they are not accessible to any unauthorized person.

3. On making out a prescription for medicaments for an individual consumer, a physician or dentist shall, unless there is some reason to the contrary, enter the name and date of birth of the person for whom the medicament is intended. A veterinary surgeon shall enter the name of the animal's owner and the species of animal. If a substance referred to in Schedule II of the Board of Social Welfare Notice giving Schedules of Narcotic Drugs is prescribed, the address of the patient or of the animal's owner shall also be entered.

If the medicament ..... is to be held.

9. The person making out the prescription may, by endorsing the form, prescribe repeated dispensing (iteration) of a medicament which does not consist either of a substance referred to in Schedule II of the Board of Social Welfare Notice giving Schedules of Narcotic Drugs and/or of technical spirits. Such an endorsement shall not cover more than three iterations and shall, if this is deemed appropriate,

require that the medicament shall not be dispensed again until a certain minimum time has elapsed. The number of iterations shall be stated in words. The iteration of free medicaments which are referred to in the Order of 4 June 1954 (No. 519) c/ concerning Medicaments Free of Charge or at Reduced Prices shall be subject to the provisions laid down separately on the subject.

This Notice shall enter into force on 1 July 1972.

Alsén, Liljestrand, Langton, Wahlqvist, Böttiger, Krook

(Bureau L 1)

c/ MF 1954: 107. Björkquist-Rahm: Medicinalförfattningar, p. 979.