



UNITED NATIONS

E/NL 1952/102-103
22 October 1952

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

ETHIOPIA

COMMUNICATED BY THE GOVERNMENT OF
ETHIOPIA

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.

New York, 1952

ETHIOPIA

Nº 24 of 1942

A PROCLAMATION GOVERNING THE SALE AND IMPORTATION OF CERTAIN DRUGS

1. This Proclamation may be cited as the Dangerous Drugs Proclamation.
2. No person shall import opium, coca, cannabis indica or datura, or any of their alkaloids or derivatives, or heroin, without a permit issued by the Minister of Commerce and Industry on the advice of the Director of Medical Services.
3. None of the drugs mentioned in Article 2 hereof shall be offered for sale except in a pharmacy or drug-store which is licensed according to the law.
4. No persons shall sell any of the drugs mentioned in Article 2 hereof unless they have been prescribed by a medical practitioner who is registered and licensed according to the law.
5. Any person who contravenes the provisions of this Proclamation is guilty of an offence and shall be liable on conviction to a fine not exceeding dollars 2,000 or to imprisonment for a period not exceeding 2 years, or to both such fine and imprisonment.

Done at Addis Ababa this 23rd day of September, 1942.

E/NL.1952/103

Notice to all pharmacies in Ethiopia

Until further regulations will be published the following temporary Rules are hereby given in order to regularize pharmaceutical routine and maintain a high professional and ethical standard in the pharmacies in Ethiopia.

These instructions shall pertain, in applicable parts, also to Institutions which although not managed by a pharmacist deliver medicaments.

Paragraphs 4, 5, 15, 13, 14, 17, 18, 20(a), 21, 29, and 30 shall also pertain to any person, society, company or similar licensed to import, manufacture or sell medicaments and to the premises where such business is carried out.

1. The Pharmacy must at every time during office hours be personally supervised by a duly licensed pharmacist assisted by the following minimum staff:- one assistant, one attendant and/or bottle cleaner.

2. Office hours shall be:-

- A. For hospital pharmacies as stipulated by the Director of the hospital.

- B. For a private pharmacy which is not on night and holiday duty

Weekdays:

From: not earlier than 0800 o'clock but not later than 0830 o'clock.

To: not earlier than 1230 o'clock, but not later than 1300 o'clock.

and

From: not earlier than 1430 o'clock, but not later than 1500 o'clock.

To: not earlier than 1800 o'clock, but not later than 2000 o'clock.

C. For private pharmacy which is on night and holiday duty:

From: 0600 o'clock to 0900 o'clock

and

From: 1230 o'clock to 1500 o'clock

and

From: 1930 o'clock to 0600 o'clock the next morning.

During other hours the entrance-door may be closed, provided that on ringing the night-bell the pharmacist can appear in the pharmacy within half an hour.

Sundays and Holidays

From: 0600 o'clock day and night (24 hours) on which days all other pharmacies shall be closed.

3. The Pharmacist must always be present during the working hours of his pharmacy.

4. No unauthorized person shall enter behind the delivery-counter or into the laboratory or into any other place not accessible for the public.

5. The premises of a pharmacy etc. shall always maintain a high hygienic and sanitary standard and comply with all hygienic rules which are or may be prescribed by the Government or by Local Authorities. Thus the pharmacy etc. must present an atmosphere of absolute cleanliness, neatness and good order. The public floor area must not be used as a storage place.

6. The pharmacist and his assistant shall wear clean white gowns when on duty.

7. The pharmacy premises shall be equipped with running water, a sink with a drain to carry off waste liquid and a special basin for handwashing.

8. A water-closet shall be installed in the pharmacy or its immediate vicinity.

9. A public pharmacy shall be equipped with potable water for the convenience of the public.

10. Every pharmacy shall be equipped with a minimum supply of laboratory utensils and other pharmaceutical instruments and apparatus as listed in Supplement III to this notice. A pharmacy not complying with this paragraph is not permitted to prepare any compounded prescriptions whatsoever and the professional activity thereof is limited to that of selling pharmaceutical specialities.

The proprietor of the pharmacy is given a respite of six months from the receiving of this notice to make the necessary arrangements to comply with paragraphs 7, 8 and 10.

11. No pharmacy shall be used as living quarters for any person, provided that this does not apply to one room being used as temporary bedroom during night-duty subject to this room being kept in a hygienic state.

12. The following pharmaceutical terms are defined in Supplement IV to this notice (1) Drugs, (2) Chemicals, (3) Medicaments (4) Pharmacy Drugs, (5) Common Household Drugs, (6) Pharmaceutical Specialities.

13. The narcotics as defined in Supplement V to this Notice shall be kept locked in a

cupboard or depository bearing the word "NARCOTICS" painted in easily read letters in Amharic and English. The key to the cupboard or depository shall always remain in possession of the responsible person duly licensed as pharmacist or as importer or seller or manufacturer of medicaments.

14. All poisons shall be kept separated from non-poisonous drugs and locked, the containers being labelled with the skull and cross bones and the word "POISON" in English and Amharic. Every preparation containing one or more of these substances in excess of the official therapeutic dose must be supplied in a container labelled in the same way.

For the advantage of the pharmacists the list of poisons in the American Pharmacopoeia Edition XIII (Officially accepted in Ethiopia) and the list of poisons in the Italian Pharmacopoeia Edition V used in Ethiopia until the adoption of the American Pharmacopoeia, are attached to these Pharmacy Rules as Supplement 1 and 2. Any other poisons shall be kept and sold according to the above mentioned Rules.

Preparations intended only to be used externally shall be labelled "CAUTION - FOR EXTERNAL USE ONLY, NOT TO BE TAKEN INTERNALLY" in Amharic and English. Caustics and inflammable substances will be kept locked and labelled "POISON - DANGEROUS USE ONLY ACCORDING TO INSTRUCTIONS" in Amharic and English.

The pharmacists shall not hand preparations containing poisonous substances intended to be used only externally, caustics and inflammable substances, to minors (i.e. to persons who are or seem to be under 18 years of age) or to persons, who seem to be incapable of responsibility.

15. A register of narcotics shall be kept in which the pharmacist or the licensed person shall enter without delay any import, purchase or acquisition, manufacture, transfer, composition and sale of such drug giving all details as dates, amount name of the source of acquisition, of persons prescribing or requiring the drug and of the patient or customer. This register and verifications shall be kept at least five years and shall be available on request for scrutiny by a Representative of the Ministry.

16. Narcotics, poisons and contraceptive preparations shall be delivered only on prescription written by a medical practitioner (doctor, veterinarian or dentist) duly registered in Ethiopia. It shall not be lawful to prescribe or to repeat a request for narcotics and poisons by telephone.

17. Prescriptions and requests for narcotics, poisons and contraceptive preparations shall be kept at the pharmacy or at the premises of the importer, manufacturer and seller as verification together with the register.

18. Prescriptions of medicaments containing poison (except narcotics) shall be copied in a special register, this register being kept as prescribed for the narcotic register in paragraphs 15/19 (a). The prices for medicaments shall not exceed the prices lawfully authorized by the Ministry of Commerce and Industry (controlled price).

19. The pharmacist shall before delivery write the price on the prescription form together with the data and his register.

20. A copy of the U.S.P. last valid Edition shall be available at all times at the pharmacy and premises of the manufacturer and seller.

21. No person, except a duly registered pharmacist may prepare, compound or deliver a prescription from a pharmacy; provided that his assistant or an apprentice shall be allowed to prepare or compound a prescription containing only non-poisonous ingredients under the personal supervision of the pharmacist and on his responsibility. Powders containing poisonous ingredients shall be dispensed by weighing the powders separately; dispensing by mere estimation of weight is not allowed. Maximum deviation for powders containing poisonous ingredients 2%, for others 5%.

22. (A) Prescriptions shall be prepared as soon as possible and exactly according to the prescriber's order. Adulteration, the affixing of incorrect brand names or substitution of any kind is strictly forbidden. If the handwriting of the prescriber is illegible, or the prescription is obscure, or if the prescriber's intention is not

known or there is doubt as to some technical matters concerning the compounding of the prescription, the pharmacist shall refuse to deliver it until he has conferred with the prescriber.

The proprietor of the pharmacy shall have in stock or, on request by a legitimate prescriber, immediately order, all drugs and compounds mentioned in the U.S.P. last official revision. However, the proprietor shall on request immediately order any pharmacy drug provided that its sale is lawfully authorized and that he can purchase them at a price giving him reasonable profit without exceeding the lawfully authorized controlled prices.

(B) It shall be strictly forbidden for the pharmacist to discuss or criticize the prescribers order with a customer, as this is beyond the bound of the pharmacist's professional knowledge, neither may he reveal what he may perceive from the remedies prescribed concerning the customer's disease to the latter nor may he show the prescription or his perception thereof to any one whosoever not concerned.

(C) It is strictly forbidden to pharmacists to pretend to possess medical skill or carry out medical practice or treatment. It shall, however, be understood that this does not prevent a licensed pharmacist in emergency, and, if a medical practitioner is not available, from giving advice and help to the best of his knowledge and common sense.

23. No prescription containing narcotics or first class poisons shall be repeated unless the customer presents a new prescription form written by a duly licensed prescriber.

24. The pharmacist shall before delivery of a medicament on prescription affix to the container or package a label containing:

- (a) The name of the patient (or initials may be used in special cases)
- (b) The name of the articles or the ingredients using the nomenclature of the U.S.P. last valid Edition.
- (c) The directions for use as written by the prescriber.
- (d) The name of the prescriber and the pharmacist.
- (e) The date.
- (f) The price according to paragraph 19.
- (g) The label with the skull and cross bones and the word "POISON" in English and Amharic, if the medicine contains poison.
- (h) Any other direction which may be required for technical matters such as "TO BE SHAKEN" or "TO BE STORED IN A COOL PLACE" etc.

25. The directions for use shall be written in Amharic or, if the patient request, in English.

26. The label shall be of a white colour for medicaments intended for internal use and of a red colour for medicaments intended for external use.

27. Medicament for internal use means a medicament intended to be taken by mouth, to be given by injections or to be given by rectum. Medicament for external use means a medicament which is intended to be given in any other way than internally.

28. The rules laid down in paragraphs 24 and 25 enter into force immediately. Regarding paragraph 26 the proprietor is given two months respite from the receipt of this Notice to buy the red labels.

29. The pharmacists etc. shall be willing at all times to have their premises and records inspected and examined by a Representative of the Ministry of Public Health. Any criticism or suggestions will be handed to the pharmacy in writing.

30. Any person who wilfully acts in contravention of, or fails to comply with the provisions given in these Rules shall be guilty of an offence against the Ministry of Public Health and shall be liable to a severe reprimand and warning and, if repeated, his licence shall be cancelled in accordance with the Proclamations in the Negarit Gazeta.

SUPPLEMENT I

LIST OF POISONS INCLUDED IN THE AMERICAN PHARMACOPOEIA EDITION XIII

Amylnitrite	Hyosciamus
Antimony Potassium tartrate	Hyosiciamus Tincture
Antimony Sodium Thioglycollate	Iodine
Antimony Sodium Thioglycollate injection	Strong Iodine Solution
Apomorphine Hydrochloride	Ipecac
Arsenic Trioxide	Ipecac Fluid Extract
Atropine	Lead Acetate
Atropine Sulfate	Yellow Mercuric Oxide
Barbital (Veronal)	Mild Mercurous Culorids
Barbitral Sodium (Veronal Sodico)	Ammoniated Mercury
Belladonna Extract	Mercury Oleate
Belladonna Leaf	Methachlorine Chloride
Belladonna Tincture	Morphine Sulfate
Butacaine Sulfate	Neostigmine Bromide
Garbacol	Opium
Chromium Trioxide	Granulated Opium
Cocaine	Powdered Opium
Cocaine Hydrochloride	Opium Tincture
Codeine Phosphate	Ouabain
Codeine Sulfate	Papaverine Hydrochloride
Colchicine	Pentobarbitol Sodium
Digitalis	Phenobarbital
Digitalis powdered	Phenobarbital Sodium
Digitalis Tincture	Phenol
Digitoxin	Physostiomine Nitrate
Dihydromorphinone Hydrochloride	Potassium Arsenite Solution
Diphenyl Hydanton Sodium	Potassium Hydroxide
Emetine Hydrochloride	Quinacrine Hydrochloride
Ephedrine	Scopolamine Hydrobromide
Ephedrine Hydrochloride	Silver Nitrate
Ephedrine Sulfate	Toughened Silver Nitrate
Epinephrine	Sodium Hydroxide
Ergonovine Maeate	Stramonium
Ergotamine Tartrate	Stramonium Extract
Erythrityl Tetranitrate	Stramonium Tincture
Ethylmorphine Hydrochloride	Strichnine Sulfate
Eucatropine Hydrochloride	Trichloracetic Acid.
Homatropine Hydrobromide	Pilocarpine Nitrate
Hydrochloric Acid	

LIST OF POISONS INCLUDED IN THE ITALIAN PHARMACOPOEIA EDITION V

Acido Agarico	Estratto segale Cornuta
Aconitina	Etilmorfina Cloridrato
Adrenalina	Fosfore
Adrenalina Cloridr. Sol 1%	Idrastina Clororo
Agaricina	Laudano
Amile Nitrito	Liquore Arsenicale Fowler
Anidride Arseniosa	Liquore Arsenicale di Pearson
Antimonio e Potassio Tartrato	Liquore Arsenicale di Van Swieten
Apomorfina Cloridrato	Sali di Mercurio
Argento Nitrato Crist.	Morfina Cloridrato
Argento Nitrato Fuso	Noce Vomica
Atropina Solfato	Olio Crotoniglio
Canape Indiana	Olio Fosforato
Cantaridina	Omatropine Bromidrato
Coca Foglie	Oppio
Codeina e Sui Sali	Pastiglie di Cloruro Mercurico
Diacetilmorfina Cloridr.	Pilocarpina Cloridato
Emetina Cloritrato	Podofillina
Eserina Salicilato	Polvere Del Dower
Astratto Aconito	Sciroppo di Morfina
Estratto Belladonna	Sciroppo di Oppio
Estratto Belladonna Secco	Scopolamina Bromidrato
Estratto ca Cape Indiana	Sodio Arseniate
Estratto Colchio	Sodio Cacodilato
Estratto Coloquintide	Sodio Metilasrsinato
Estratto Giusquiamo	Stricnina Mitrato
Estratto Noce Vomica	Tintura di Canape Indiana
Estratto Oppio	Tintura di Coca
Estratto Opio Fluido	Tintura di Oppio
Estratto Segale Cornuto	Verstrina

SUPPLEMENT III

LIST OF MINIMUM SUPPLIES OR OBLIGATORY LABORATORY UTENSILS AND OTHER PHARMACEUTICAL INSTRUMENTS AND UTENSILS

- 1 Prescription balance, all metal, sensitive and accurate, max. load 200 grams.
- 1 Set of precision weights, complete from 1 mg. to 200 grams, the flat weight of aluminium or silver, the cylindrical weight of brass or stainless steel.
- 1 Prescription balance, sensitive and accurate, max. load 2 kg.
- 1 Set of precision weight, complete from 1 gr. to 2 kg. cylindrical made of brass or stainless steel.
- 1 Linear measure. Length 5 dm. divided into dm. and cm. 1 dm. divided into mm.
- 1 Pill machine with grooves of 2 different sizes.
- 1 Spirit lamp
- 1 Alcohol blast lamp.
- 1 Stove (furnace) electric or primus
- 5 Mortars and pestles of different sizes for trituration, made of porcelain
- 5 Mortars and pestles of different sizes for emulsion and ointments etc.
The mortar being made of porcelain, stainless or enameled iron, the pestles of porcelain.
- 10 Spatulas for ointment and pills.
- 1 Rotary grater
- 1 Suppository compressing machine, giving two sizes
- Thermometers, showing the temperature from 20.6 to 360 C
- 1 Water bath
- 1 Retor-stand with clampholders, clamp-extensions and different rings
- 1 pair of crucible tongs
- Crucible of porcelain with cover
- Pipe clay triangles
- Tripod stands
- 2 Burettes 25 and 50 cc divided in tenths of cc.
- 3 Pipettes, 10; 25. and 50 cc.
- 3 Pipettes 10 cc divided in tenth of cc.
- 1 Pipette, 1 cc, divided in hundredths of cc (not obligatory)
- 1 Pipette, 2 cc divided in half of cc.
- 5 - 10 Flat Bottom round glass, capacity 50, 100, 250, 500 and 1000 cc.
- 6 - 12 Flat Bottom conical glass flasks (Erlenmeyer) volumetric 50, 100, 250, 1000, 500 and 2000 etc.
- 4 - 8 Glass beakers holding 25, 50, 100, 250 etc.
- 7 - 4 Cylindrical graduates of glass measuring 10, 25, 50, 100, 250, 500, 1000 cc. divided in cc.
- Dishes of various sizes, porcelain and glass
- Glass tubes and glass rods
- 10 Glass funnels of various capacity from 10 cc to 1000 cc.
- Filter paper, round different sizes
- Cork borer
- Cork tongs
- 100 Test tubes, outer diam 16-20 mm.
- Test tube stand.

DEFINITIONS

1. *Drugs* when not otherwise limited means all substances used as medicines or in the preparations of medicines.
2. *Chemicals* when not otherwise limited means the chemical materials of medicines.
3. *Medicament* when not otherwise limited, means any product intended to be used to prevent, indicate, mitigate or cure illness or disease or their symptoms in men or animals.
4. *Pharmacy Drugs* when not otherwise limited, means all chemicals and drugs which are exclusively or essentially used as medicaments or with preparation of medicaments.

All simple drugs belonging to this paragraph, see List 1.

Examples of compounds belonging to this paragraph, see List 2.

5. *Common Household Drugs* when not otherwise limited means any drug, chemical, medicine, or poison which all general merchants may sell. See List 3.
6. *Pharmaceutical Specialities* means a drug, chemical or medical, serum, vaccine or other bacteriological preparation which generally must not be sold to private consumer elsewhere than from a pharmacy and is supplied to the consumer in the same original sealed package in which it has been delivered by the manufacturer.

List No. 1 Pharmacy Drugs. Index or simple drugs. (This list will be fixed by the Ministry of Public Health for the future and revised yearly). On written request the Ministry of Public Health will give its decision whether an article is a "Pharmacy Drug" or not.

List No. 2 Pharmacy Drugs. Examples of compounds:

- A. Food preparation mixed with medicine
- B. Organotrapeutic preparation
- C. Pharmaceutical specialties
- D. Any other preparation or compound which is *only* or *mostly* used as medicament with exception given in List No. 3

<i>Examples</i>	Capsules	Pastilles
	Decoctions	Pills
	Electuaries	Plasters
	Emulsions	Powders - Mixed
	Extracts	Solutions
	Hemopatic Med.	Suppositories
	Infusions	Syrups
	Liniments	Tablets
	Mixtures	Tinctures
	Ointment	Troches
	Pastes	Vegetable Drugs - Mixed.

List No. 3 Common Household Drugs

- (a) Cosmetic preparations intended to be used to dress or take care of the external appearance or to clean the cavity of the mouth.
- (b) Preparations against corne
- (c) Disinfectants intended to be used for disinfecting only.
- (d) Dressing materials all kinds, unimpregnated or pregnated.
- (e) Mineral water, natural and artificial.
- (f) Salts from mineral springs, natural and artificial, and fruit salts, not mixed with medicine.
- (g) Food preparations not mixed with medicine.
- (h) Preparations intended to be used to dress or clean non-infected wounds.

- (i) The following exemptions from List No.2 (This List is fixed by the Ministry of Public Health and revised twice a year):
Certain plasters,
Certain liniments,
Certain solutions,
Certain tablets, pastilles and Roches Losenges; medicinal candy or similar,
Certain dentals drops.
- (j) Other medicinal preparations that the Ministry of Public Health from time to time deems fit to be sold as Common Household Drug.
On written request the Ministry of Public Health will give its decision whether an article is a "Common Household Drug" or not.

SUPPLEMENT V

NARCOTIC DRUGS

Until further Regulations are issued the Rules concerning Narcotics pertain to any pharmaceutical speciality included, containing

1. *Opium*, raw and medicinal and preparations containing more than 20 per cent of morphine.
2. *Morphine*, pure and crude, its salts, ester and ethers, preparations containing more than 0.1 per cent and solutions and dilutions, even if they contain 0.2 per cent or less.
3. *Diacetylmorphine* (Heroin) its salts and preparations.
4. *Coca leaves*
5. *Cocaine*, pure, crude, salts, preparations containing more than 0.1 per cent, solutions and dilutions even if they contain 0.1 per cent or less.
6. *Dihydrocodeine* (Eukodal) its salts and esters and their preparations.
7. *Dihydrocodeine* (Dicodide) its salts and esters and their preparations.
8. *Dihydromorphine* (Dilaudide) its salts and esters and their preparations.
9. *Acetyldihydrocodeine* (Acedicone) its salts and esters and their preparations.
10. *Dihydromorphine* its salts and preparations.
11. *Morphine-Noxide* its salts and preparations other than pentavalent nitrogen morphine derivative and their preparations.
12. *Methymorphine* (Codeine) and its salts.
13. *Ethylmorphine* and its salts (Dionine).
14. *Indian Hemp*. its resin and preparations.

Any product which by Public Notice made by the Ministry of Public Health is classified as or equal with a narcotic drug.

NOTICE TO ALL LICENSED DOCTORS, VETERINARIANS AND DENTISTS.

Until further regulations have been issued, the following instructions are hereby given in order to regularize prescribing of medicaments and any pharmacist is hereby authorized to refuse the delivery of prescriptions or requests not complying with this Notice.

1. A prescription shall be written plainly and without abbreviations or signs which could make its contents in any way obscure or ambiguous.
2. A prescription shall be written in a legible handwriting and shall contain the signature of the prescriber, full name, in block letters, and title.
3. Prescriptions shall contain: (1) Name of the patient and also if it is prescribed

- for a child, its age (2) full direction for use.
4. The ingredients shall be written in English or Latin using as far as possible the Nomenclature of the U.S.P. Last Edition, for non-official remedies, name in the near conformity with the said Nomenclature. The doses shall be given by the Metric System. Doses exceeding the double average doses of the U.S.P. of for non official drugs in double usual average doses shall be underlined and indicated with the word "SIC".
 5. Veterinarians prescriptions shall bear the heading "For Veterinarian use only".
 6. Dentists prescriptions shall bear the heading "FOR DENTIL TREATMENT ONLY".
 7. No prescriptions shall be made by telephone.
 8. Prescriptions containing poisons or narcotics shall be delivered only once. The same applies for prescriptions containing non-poisonous ingredients if the prescriber has made such a written annotation.
 9. Prescription forms containing narcotics or poisons shall contain one formula only on each paper and shall not be reiterated unless on a new prescription form.
 10. A prescription shall be written on one side only of the paper.

It shall be strictly forbidden for any doctor, veterinarian or dentist to enter into any economical agreement with a pharmacist or druggist, manufacturer or wholesale firm dealing in medicines:

It shall be forbidden for any proprietor of a pharmacy to enter into any economical agreement with a medical practitioner (doctor, veterinarian, or dentist).

The term economical agreement is understood to mean amongst other things: financial investment, accepting of financial commissions, splitting of fees, referring patients to a special doctor or a special pharmacy, etc.

MINISTRY OF PUBLIC HEALTH

Addis Ababa, 10th June 1950
3rd Sené 1942