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LAWS AND REGULATIONS

PROMULGATED TO GIVE EFFECT TO THE PROVISIONS OF THE CONVENTION OF 13 JULY 1931 FOR LIMITING THE MANUFACTURE AND REGULATING THE DISTRIBUTION OF NARCOTIC DRUGS, AS AMENDED BY THE PROTOCOL OF 11 DECEMBER 1946

PORTUGUESE GUINEA

Communicated by the Government of Portugal

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.

ORDER OF THE GOVERNOR IN COUNCIL NO. 1:422 of 7 JULY 1948

Considering that pharmacy in Portugal should be given the social standing it merits, not only by reason of the quality of its practitioners, but also because of its essential note in safeguarding public health;

Considering that pharmacy has recently made great progress and has greatly changed medical and chemical therapy, thus introducing new technical, professional and economic trends;

Considering that the practice of pharmacy is not properly organized in Guinea and that it is consequently necessary to make comprehensive regulations, consolidating and bringing up to date the scattered legislation, establishing new rules and setting up appropriate and essential control machinery;

Considering the advantage of combining in a single order all the provisions regulating the profession and practice of pharmacy and the preparation and sale of proprietary pharmaceutical preparations and narcotic drugs;

On the proposal of the Central Department of the Health Services;

Having consulted the Council of Health and Hygiene, and with the concurrence of the Governing Council, the Governor of the Colony of Guinea, in exercise of the powers vested in him by articles 28 and 30 of the Colonial Act and by article 43 of the Organic Charter of the Portuguese Colonial Empire, hereby orders as follows:

REGULATIONS GOVERNING THE PRACTICE OF PHARMACY IN PORTUGUESE GUINEA

CHAPTER I

The Profession and Practice of Pharmacy

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Article 12

The supply of medicaments or medicinal substances to the public in any form in containers or wrappers which are not properly labelled is strictly prohibited.

1. The name of the medicament or medicinal substance, the quantity, the price and the number in the appropriate register shall be shown on the label.

2. In the case of proprietary preparations, the provisions of articles 39, 44 and 45 shall be complied with.

3. The wrappers of medicaments and medicinal substances for external use shall bear a rectangular label with the words "For external use" printed in black on a red ground.

4. The wrappers of medicaments and medicinal substances for veterinary use shall bear a rectangular label with the words "For veterinary use" printed in black on a green ground.

5. The wrappers of medicaments containing any substance which may not be supplied in doses larger than the normal dose without a medical prescription shall bear a triangular label with the words "Do not exceed the dose" printed in white on a blue ground.

6. The wrappers of medicaments and medicinal substances containing any poison shall bear a triangular label with a skull and the word "Poison" printed in white on a black ground.

Article 13

The bottles, pots, boxes and other containers in which medicaments and medicinal substances are packed in pharmacies must be suitably and legibly labelled and may not be displayed in show cases or windows.

1. Proprietary preparations, surgical instruments and materials, remedies for external application, pharmaceutical accessories and products for hygiene, prophylaxis and perfumery may, however, be displayed to the public.

2. These provisions shall apply to druggists, to wholesale suppliers or manufacturers of medicaments and medicinal substances, to stockists or import agents and to establishments coming within the scope of article 22 of this Order and the sections thereof.

Article 14

Every pharmacy must possess the latest edition of the Portuguese Pharmacopoeia, price list, official formulary for the Colony and the medicaments, accessories and remedies for external application marked as essential in the price list.

Article 15

The medicaments and medicinal substances included in the Portuguese Pharmacopoeia may be sold only under the names given therein, except when prescribed under a name in common use which cannot be confused with any other similar name.

Article 16

The Inspectorate of Pharmacy shall cause to be obtained from pharmacies, laboratories, agents, druggists, establishments within the scope of article 22 and others dealing in or manufacturing pharmaceutical products, samples of medicaments, whether proprietary preparations or not, and of medicinal substances and products for hygiene or prophylaxis, whenever it deems necessary to do so in order to carry out an official investigation of their composition, degree of purity and efficacy.

Sole Section. The Inspectorate of Pharmacy shall require the competent authorities to comply with the provisions of this article whenever it sees fit.

Article 17

Medicaments and medical substances may not be advertised in medical or pharmaceutical publications (whether published regularly or irregularly) or in any other publications or advertising media, unless the wording of the advertisements has first been approved and authorized by the Inspectorate of Pharmacy.

1. The persons responsible for the publications or advertising media shall require the advertiser to produce the necessary authorization and shall be held responsible for non-compliance with this article.

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Article 18

Subject to the exceptions provided for in this Order, medicaments, proprietary pharmaceutical preparations and medicinal substances, may be sold to the public by pharmacies only. It is strictly prohibited for druggists or any other establishments to dispense prescriptions, prepare medicaments or sell serums, vaccines, biological diagnostic agents or similar products to the public.

1. The wholesale supply of medicaments may be undertaken by pharmacies only.

2. Druggists and establishments authorized to import as agents or stockists for laboratories making pharmaceutical products, whether proprietary preparations or not, may not supply medicaments wholesale unless they have a qualified pharmacist in charge of the department so doing. The provisions of this section shall take effect only when the Governor considers it advisable.

3. The import and sale of new medicaments and new foreign proprietary preparations not yet tested in any territory of the Portuguese Colonial Empire shall be subject to authorization granted by the Health Services on the basis of information supplied by the Inspectorate of Pharmacy. This branch of the trade shall be subject to the following regulations:

(a) For the purpose of this section, pharmacies, druggists and other establishments authorized by law to stock medicaments are required to apply for authorization to the Head of the Health Services, submitting samples of the preparations in question before they are cleared through the Customs, for analysis or other tests.

(b) The Health Services may refuse an import licence and withdraw authorization to sell medicaments or proprietary preparations which are considered harmful. An appeal from the decision of the Health Services may be made to the Governor of the Colony.

(c) Medicaments of foreign origin, whether proprietary preparations or not, which have not yet been tested in any territory of the Portuguese Colonial Empire, shall be analysed on entering the Colony, if possible at the Health Services' Laboratory for Chemical, Nutritional and Toxicological Analysis, in order to verify their quantitative and qualitative composition, one unit in each consignment being tested.

4. The charge for such analysis shall be 100 escudos.

5. The authorization referred to in the body of section 3 shall be deemed to be permanent, unless the Health Services decide to the contrary.

6. Drugs and chemical products not used exclusively for therapeutic purposes may, provided that they are intended for other purposes, be imported without authorization from the Health Services.

7. A fee of 70 escudos shall be charged for every licence to import medicaments or proprietary preparations.

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Article 20

Pharmacies must keep a register of all prescriptions dispensed, clearly and accurately copied, and showing the serial number of each prescription, the date of dispensing, the cost of the ingredients and the names of the customer and prescribing doctor.

1. Medicaments sold direct to the public without a medical prescription shall be entered in a separate register with particulars of the date, quantity and cost of each medicament.

2. These registers, and all others kept in a pharmacy, shall be certified by the competent Inspector of Pharmacy in the regular form. A fee of 30 escudos shall be charged for each page countersigned or stamped.

Article 21

The stamp of the pharmacy, the date of dispensing and the cost of the ingredients must be entered on each prescription, which must first be copied into a separate register and given a number.

Article 22

At places where there is no private pharmacy open to the public, local traders may be authorized by the Health Services, acting on information from the Inspectorate of Pharmacy, to sell, in general stores, authorized proprietary pharmaceutical preparations and the medicaments on the list annexed to this Order, in the original wrapping, properly labelled and in the quantities specified

in the list, or to open a druggist's shop for the purpose.

1. To comply with this article, the shop must be equipped with suitable cupboards with windows, bearing the following notice at the top in white enamel on a black ground: "Medicaments and proprietary pharmaceutical preparations - authorized sale".

2. Supplies of medicaments and proprietary preparations for the establishments referred to in this article shall at all times be under strict supervision by inspectors of the Inspectorate of Pharmacy or, failing such inspectors, by agents of the Health Services, who shall check the orders and deliveries, which must always agree.

3. The aforesaid authorizations shall be valid for the place referred to or for any other place not more than 30 kilometres distant therefrom if no private pharmacy has been opened; a period of six months from the date when a pharmacy is opened shall be allowed for closing the establishments referred to in this article.

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Article 25

All pharmacies and pharmaceutical laboratories must display the name of the pharmacist who is technical manager in easily legible lettering outside and inside the building. His name must also appear on labels, stamps, bills, order-forms and any other documents of which the pharmacy or pharmaceutical laboratory makes public use.

CHAPTER II

Laboratories

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Article 32

Any medicaments manufactured in contravention of the provisions of this Order shall be confiscated by the Inspectorate of Pharmacy and placed at the disposal of the social welfare authorities, without prejudice to the submission of a report on such confiscation to the competent court for judgment.

CHAPTER III

Pharmacists' technical assistants

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CHAPTER IV

Proprietary Pharmaceutical Preparations

Article 38

The manufacture of proprietary preparations shall be subject to authorization by the Health Services, issued after consulting the Inspectorate of Pharmacy. A licence shall be deemed permanent, unless the Health Services decide otherwise.

1. To this end, any person wishing to manufacture proprietary preparations is required to submit an application to the Head of the Health Services, accompanied by a description giving adequate particulars of the composition and use of the preparation signed by a qualified pharmacist or pharmaceutical chemist and to pay a fee of 100 escudos. The application shall be investigated by the Inspectorate of Pharmacy or the Veterinary Department, according to whether the preparation is for human or veterinary medicine. The applicant shall also submit samples of the preparation for qualitative andquantitative analysis of its constituents in the State laboratories, when this is considered necessary. On completion of this preliminary procedure, the Head of the Health Services shall grant or refuse the requested authorization.

2. Where no method of analysing the composition of a preparation is known, and a need for the preparation is considered to exist, the Head of the Health Services may authorize its import after consulting the bodies referred to in the preceding section.

Article 39

Proprietary preparations may not be placed on sale unless their active ingredients and the percentages thereof are specified on the label, together with the name of the manufacturing pharmacist, the place of manufacture and the name of the manufacturer's agent.

Article 40

Proprietary preparations placed on sale without having their composition verified as provided in articles 38 and 39 shall be confiscated by the Inspectorate of Pharmacy and placed at the disposal of the social welfare authorities, a report on the case being drawn up.

Article 41

The Head of the Health Services, having consulted the bodies referred to in this Order, may authorize the waiving of formalities for the import of proprietary preparations for the Health Services, Veterinary Services or State Welfare Department, or for experiments in hospitals or laboratories.

Article 42

Samples intended for doctors, veterinarians and pharmacists shall be exempt from the provisions of this Order.

Article 43

The sale to the public of samples,in particular those labelled "Free Sample", is strictly prohibited.

Article 44

The prices in escudos at which proprietary preparations are to be sold to the public shall be indelibly stamped in easily legible figures on the wrappings, labels or tags.

Article 45

The selling prices of proprietary preparations manufactured in the Colony shall be printed in easily legible figures on the label, wrapper or tag.

Article 46

For the purposes of this Order, the term "proprietary pharmaceutical preparation" shall be understood to mean any substance, domestic product or medicament, simple or compound, in any pharmaceutical form, packed in the original wrapper or container in which it is sold direct to the public for therapeutic purposes without undergoing any further processing or pharmaceutical change, whether or not it bears a registered trade mark or the formula of its composition inside or outside, on the container, wrapper or label.

CHAPTER V

Poisons and Narcotic Drugs

Article 47

Narcotic drugs may be imported or exported only by the following:

(a) Lawfully established pharmacies;

(b) The Health Services;

(c) Pharmaceutical manufacturing laboratories.

Article 48

In the Customs houses of the Colony the import for consumption and the export of the drugs and products on List C annexed hereto, are allowed only in accordance with the provisions of this Order.

1. The Governor may amend or supplement List C annexed to this Order after consulting the Board of Health and Hygiene.

2. When the countries of origin so require, the Government of the Colony shall certify that the products to be imported are intended for legitimate medical or scientific purposes, as provided in article 52 of this Order, and that they will not be re-exported.

Article 49

The import, cultivation, sale and consumption of Cannabis sativa (L) are strictly prohibited.

Article 50

Establishments of the kinds specified in article 47 which wish to engage in import trade in drugs on List C annexed to this Order must apply to the Governor of the Colony, through the Health Services, for authorization. After it has been dealt with, the application shall be sent to the Inspectorate of Pharmacy, where it shall be filed.

1. If the applicant is an establishment such as is specified in sub-section (a) or (c) of article 47, the application must be signed before a notary and must give the registration number of the pharmacy or laboratory.

2. The applications shall be filed at the Inspectorate of Pharmacy, separate action being taken on each one, and the importing establishments being entered in a separate register.

Article 51

Whenever an importer, having been duly authorized and registered in accordance with article 50 and the sections thereof, wishes to import any of the drugs referred to therein, he must apply to the Government of the Colony, through the Health Services, for an import licence.

Sole section. The application must specify the name and quantity of the drugs to be imported, the Customs house through which they are to pass, the name of the manufacturer and the route by which they are to be consigned. If the drugs are not pure alkaloids or if they are compounded proprietary preparations, the percentage of constituent alkaloids in each drug or compound must be specified. Whenever it is deemed necessary, applicants shall submit samples for confirmatory analysis.

Article 52

Narcotic drugs shall notbe sold or consumed, except for legitimate medical, pharmaceutical or scientific purposes.

Sole section. Doctors may order narcotic drugs from pharmacies for use in their own consulting rooms, stating the reasons in each case; they must keep a register of their own from which the use made of the drugs ordered can be easily checked.

Article 53

Pharmacies shall not supply the public with any of the narcotic drugs on List C or with any of the poisons on List D without a prescription from a doctor or a veterinarian, who, in addition to his usual signature, shall enter thereon, in easily legible writing, his full name and address and the name and address of the patient. The way in which the medicament is to be administered must also be specified.

1. No prescription containing any of the substances on List D may be dispensed more than once without written authorization from the doctor for each repetition.

2. Medical prescriptions for narcotic drugs shall be copied into a special book and shall then be cancelled with the stamp of the pharmacy and filed as vouchers for the returns referred to in article 56; a copy duly authenticated with the stamp of the pharmacy and the entry number in the special book shall be given to the patient. Supplies of narcotic drugs may not be repeated without a new prescription.

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Article 55

Pharmacists may, on their own responsibility, supply the following galenical preparations for immediate use in urgent cases: tincture of opium, Sydenham's laudanum and Dover's powder, provided that the maximum quantity supplied shall not contain more than 25 centigrammes of officinal opium. The pharmacist shall enter the quantities thus supplied in the appropriate register.

Article 56

Importers shall send the Inspectorate of Pharmacy a detailed quarterly return of the quantities of narcotic drugs imported, bought and sold, showing the names of the pharmacies, pharmaceutical laboratories and other establishments to which sales have been made and clearly specifying the amount acquired by each of them. Pharmacies shall likewise submit a quarterly return of the quantities sold and the numbers of the corresponding prescriptions.

1. The establishments referred to in article 47 shall enter all transactions in narcotic drugs in a special book. Pharmacies shall also keep a register of the corresponding prescriptions. These books, which shall be sealed or indelibly stamped by the Inspectorate of Pharmacy and countersigned by the competent Inspector, shall have no blank spaces, erasures or corrections in them; each entry shall be given a serial number and must give the name, occupation and nationality of the person to whom the drug was supplied or in any manner transferred, even free of charge.

2. State establishments, hospitals, "Misericordias" and welfare centres which have a pharmaceutical department of their own shall likewise make a quarterly return of incoming and outgoing movements of narcotic drugs for which they are responsible.

3. Pharmacists responsible for the technical management of pharmaceutical laboratories in which narcotic drugs are converted into pharmaceutical, veterinary, agricultural or industrial products must enter the quantity and quality of such products in a special register of the kind referred to in this article.

4. The quarterly returns referred to in this article and in section 2 thereof shall be sent to the Inspectorate of Pharmacy by registered post within thirty days from the end of the quarter to which they relate.

5. The Inspectorate of Pharmacy shall supply the standard forms for the quarterly returns referred to in this article and section 2 thereof.

Article 57

The re-export of narcotic drugs is expressly prohibited.

Article 58

Pharmacies and pharmaceutical laboratories in which substances referred to in article 48 are processed or converted may export their products, subject to authorization given by the Governor after consulting the Board of Health and Hygiene, which must be requested in an application containing the following particulars:

1. the name of the exporting firm;
2. the quantity and quality of the substances or preparations and the markings on the packages containing them;
3. the name and address of the consignee;

4. the method of despatch, i.e. whether by land, sea or air or by parcel post, and the Customs house through which export is to take place;

5. a declaration attesting that the import is authorized by the country of destination in accordance with its special laws and regulations on the import of such substances and preparations.

1. The Customs house through which the export takes place shall inspect the goods to see that they correspond with the quantity, quality and packing described in the exporter's application and in the permit, and shall then give the exporter a certificate to that effect.

2. The despatch of the substances exported shall be recorded and the Customs certificate shall be entered in the special book of transactions referred to in article 56, section 1.

Article 59

The following fees shall be paid for the permits referred to in this chapter:

(a) for registration of the importer: 500 escudos;

(b) for each application for import or export: 50 escudos.

CHAPTER VI

Opening Hours and Twenty-four hour Service

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CHAPTER VII

Supervision of the practice of Pharmacy

Article 66

Implementation of the provisions of this Order and of other legislation in force relating to pharmacies, laboratories, druggists and any other establishments engaged in the import of, trade in or manufacture of medicaments and medicinal substances, whether proprietary preparations or not, as also of provisions relating to the agents and individuals referred to by article 22 of this Order shall be supervised by pharmacists on the staff of the Health Services.

Sole section. For the purpose of this article, the Head of the Pharmaceutical Section shall be designated Chief Inspector of Pharmacy and the other pharmacists on the staff shall be designated Inspectors of Pharmacy.

Article 67

The duties of the Chief Inspector of Pharmacy shall be as follows:

1. To direct, guide and assign the work of the Inspectorate of Pharmacy and of its Central Committee;

2. To propose to the Head of the Health Services whatever measures he considers necessary for the proper enforcement of the law;

3. To guide and enlighten the Inspectors of Pharmacy, with whom he shall correspond directly, concerning any doubts about the interpretation of the law;

4. To inspect the pharmacies in the capital and at any places where he has no delegate or other inspector;

5. To inform the Chief of the Health Services of any defects revealed by experience in the organization of the practice or pharmacy and to propose whatever changes he deems advisable;

6. To report annually on 31 March to the Head of the Health Services everything relevant to the work of the Inspectorate of Pharmacy of the Colony during the previous year. This report may be submitted together with that referred to in article 70, section 3 of Order No. 165 of 30 December 1946;

7. To register service by technical assistants throughout the Colony on the basis of reports received from the other inspectors or direct;

8. To register, countersign and authenticate all books and other documents of the Inspectorate of Pharmacy;

9. To file the reports of the Inspectors of Pharmacy, the registers of narcotic drugs and other documents relating to the inspection and supervision of the practice of pharmacy throughout the Colony;

10. To propose to the Head of the Health Services the areas for which each Inspector shall be responsible and to define the functions of the Inspectors in places where there are more than one;

11. To draw up and submit to the Central Committee on the Practice of Pharmacy, for consideration, the directives and rules to be observed in the inspectors' reports.

Article 68

The duties of the Inspectors of Pharmacy shall be as follows:

1. To enlighten those concerned regarding any doubt that may arise on the interpretation of the law, for which purpose they may consult the Chief Inspector, with whom they shall correspond directly;

2. To inspect, at least once a quarter, all pharmacies, druggists' shops, pharmaceutical laboratories, agents, establishments within the scope of article 22 and establishments trading in or manufacturing medicinal substances in their areas;

3. To institute proceedings for fines and to apply to the competent authorities for the closing of pharmacies or pharmaceutical laboratories which are operating illegally or which are liable to sanction under article 3 and for the seizure of substances which have been altered or adulterated;

4. To collect samples of medicaments, proprietary preparations, medicinal substances and products for hygiene and prophylaxis from the establishments subject to their supervision and inspection, for analysis in the laboratories of the Health Services or of the Technical Section of the Veterinary Department, as the case may be, to which they shall apply for the required analyses;

5. To register the service of assistant pharmacists in their area and send a copy of such registration to the Chief Inspector;

6. To register and countersign all books and other documents subject to their supervision.

Article 69

An appeal against any sanctions imposed by the Inspectors may be made to the Chief Inspector and from him to the Governor, whose decision, taken after consulting the Head of the Health Services, shall be final.

Article 70

A Central Committee on the Practice of Pharmacy is hereby established, which shall consist of the Head of the Health Services, who shall be Chairman, the Chief Inspector of Pharmacy and the technical manager of a private pharmacy; an official of the Health Services shall serve as Secretary. The terms of reference of this Committee shall be as follows:

1. To examine the conditions under which the following are carried on:

   (a) import of pharmaceutical products, accessories and proprietary preparations;

   (b) domestic trade in, and production of, these articles in the Colony;

2. To guide, instruct and supervise establishments connected with the import of and trade in pharmaceutical products, bearing in mind the development of domestic industries;

3. To advise on matters submitted to it for an opinion by the Governor of the Colony and the Health Services;

4. To revise and issue schedules of fees and prices for drugs, medicaments and accessories on the official price list;

5. To prepare, revise and issue price lists for the following:

   (a) drugs and medicinal chemical products not subjected to further processing, the sale of which in their original wrappers or containers is permitted in druggists' shops and other authorized establishments;

   (b) proprietary preparations, whether domestic or foreign, accessories, remedies for local application and products for prophylaxis and hygiene on sale to the public.

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CHAPTER VIII

Penal Provisions

Article 72

The penalties for the offences specified below, unless specially prescribed in the Penal Code or separate legislation, shall be as follows:

(a) Anyone trading in medicinal drugs or any medicinal products or proprietary pharmaceutical preparations, without being legally authorized to do so, shall be liable to a fine of 500 to 5,000 escudos; when the products contain substances which may not be supplied without a medical prescription, in particular narcotic drugs, he shall be liable to a term of six months to one year of correctional imprisonment and a fine of 2,000 to 10,000 escudos;

(b) Any pharmacist supplying the public with any of the narcotic drugs on List C or any of the poisons on List D without a medical prescription or in quantities exceeding those specified in the prescription, except in the cases of urgency provided for in article 55, and any person seeking to obtain or obtaining such products by means of a prescription which has already been dispensed or a forged prescription, shall be liable to the penalties prescribed in the second part of sub-section (a) above;

(c) The penalties prescribed in sub-section (a) above shall also be applicable to unauthorized persons obtaining such products for professional or scientific use or wittingly making inaccurate or incomplete entries in the registers required under this Order, in the latter case, if the offence is due to negligence alone, the penalty shall be limited to a fine of 500 to 5,000 escudos;

(d) Owners or managers of meeting places, such as clubs, cafés, assembly rooms or other establishments of any kind for public entertainment who permit the use of, or traffic in, narcotic drugs on the premises, shall be liable to the penalties prescribed in sub-section (a) above; such establishments shall in all cases be closed for a period of not less than one year.

(e) On any prescription containing narcotic drugs or any of the substances which may not be supplied without a medical prescription, the prescribing physician is required to write clearly his name and address, the name and address of the patient and the method of

administering the medicine, failing which the prescription shall not be dispensed; any pharmacist dispensing such a prescription without these particulars or repeating it without express authorization for each repetition, shall be liable to a fine of 200 to 1,000 escudos;

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(h) Failure to comply with the provisions of articles 3, 8 and 18 shall render the offender liable to a fine of 1,500 to 3,000 escudos;

(i) Any person failing to comply with the provisions of articles 12, 13, 25 and 43 shall be liable to a fine varying, according to the case, from 200 to 1,000 escudos;

(j) In addition to the penalties prescribed for offences against the provisions of article 22 and the sections thereof, medicaments and proprietary preparations not included in List B shall in all cases be confiscated.

Article 73

The penalties prescribed in the second part of article 72, sub-section (a) shall also be applicable to:

(a) Any person selling or supplying medicaments which have deteriorated or have been adulterated or whose degree of purity or pharmaceutical efficacy does not reach the minimum standard required by the Portuguese Pharmacopoeia;

(b) Any pharmacist using substitutes for, or in any way altering the ingredients of a prescription duly signed by a legally qualified doctor;

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Article 76

A fine of 200 to 1,000 escudos shall be imposed on any pharmacist who :

(a) fails to send a copy of the register of his assistants to the Inspectorate of Pharmacy every year;

(b) fails to make a quarterly return of the movement of narcotic drugs within the prescribed time limit;

(c) fails to fill in on the label of a medicament or medicinal substance the quantity, price and serial number from the appropriate book;

(d) fails to have the scales, weights and measures he uses in the pharmacy duly inspected and stamped;

(e) refuses to show the price of medicaments he sells on the official price list when requested to do so;

(f) fails to keep the utensils he uses clean and in good condition;

(g) fails to keep the pharmacy and rooms annexed to it clean and in a condition complying with all the sanitary regulations;

(h) dispenses prescriptions in which the weights and measures are not given in the metric system;

(i) dispenses prescriptions written in any language other than Portuguese;

(j) dispenses prescriptions in which the weights are given only in figures;

(l) keeps unlawful weights.

1. The same penalties shall be incurred for:

(a) failure to comply with the provisions of articles 56 and 87 and the sections of those articles;

(b) failure to comply with the provisions of articles 5, 14, 15, 17 and 20;

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2. The same penalties shall be incurred by any doctor who:

(a) makes out a prescription with abbreviations or in any language other than Portuguese;

(b) when using a formula not contained in the Pharmacopoeia or the official formulary of medicaments, fails to write out the names and doses of the substances in full;

(c) fails to keep a proper register of the narcotic drugs he uses in his dispensary or to justify his orders for such drugs;

(d) fails to specify the weights and measures in his prescriptions in the metric system.

Article 77

Any doctor who prescribed medicaments by special designations or names in order that the prescription may be understood only by particular pharmacists or who compels patients to have their prescriptions dispensed at a particular pharmacy shall be liable to a fine of 1,000 to 5,000 escudos.

Sole section. Any pharmacist who conceals possession of medicaments, medicinal products or proprietary preparations shall be liable to the same penalty.

Article 78

Any person who, not being a qualified pharmacist, makes up or sells medicaments shall be liable to a fine of 1,000 escudos for the first offence and double that amount for any subsequent offences.

Sole section. After the second offence a term of up to six months' correctional imprisonment shall also be imposed.

Article 79

The penalties for pharmacists prescribed in this Order shall also be applicable to assistant pharmacists who, being legally qualified and authorized to do so, perform the acts and functions required of a person replacing the technical manager of a pharmacy during his lawful absence.

Article 80

Failure to apply the official price list or the prices fixed in the official schedules shall be punishable by a fine of 250 escudos; for the first repetition of the offence, the fine shall be 500 escudos, for the second repetition 1,000 escudos and for the third repetition 2,500 escudos. For any further offences the maximum fine shall be imposed and, in addition, the pharmacy shall be temporarily closed for a period to be determined by the Governor of the Colony, after consultation with the Central Committee on the Practice of Pharmacy.

Article 81

Any person or entity impeding or attempting to impede the Inspectors of Pharmacy in the execution of their duty or refusing to give any explanation or in any manner obstructing or attempting to frustrate their inspection shall be liable to the penalty prescribed in article 189 of the Penal Code, without prejudice to the disciplinary proceedings which may have to be instituted.

Article 82

Infringements of the provisions of this Order which are not expressly referred to herein shall be punishable by a fine of 100 to 2,000 escudos.

Article 83

Save in the cases specifically provided for in this Order, repetition of an offence shall be punishable by double the fine.

CHAPTER IX

General provisions

Article 84

State pharmacies shall dispense prescriptions for the public only in cases where there is no private pharmacy in the locality or if the private pharmacies specify in writing that they do not possess the medicaments prescribed.

Sole section. In such cases, the State pharmacies shall fix their charges to the public for medicaments and making up prescriptions in accordance with the official price list.

Article 85

The Central Medical Stores may supply private pharmacies with medicaments or preparations produced by the laboratories of the Health Services, when the stocks of the Health Services permit.

Sole section. The prices of products supplied under the provisions of this article shall be determined by the Health Services in consultation with the Central Committee on the Practice of Pharmacy.

Article 86

No medicinal substance may be kept for sale, stocked, sold, supplied, despatched or put into circulation except in a wrapper or container bearing its name, which must be clearly visible and so affixed that it cannot be accidentally detached.

Article 87

Any person or establishment importing or stocking medicaments for sale to private pharmacies or laboratories or to Government departments must keep the following registers and files, which shall be produced to the Inspectorate of Pharmacy on its request:

(a) a register of goods received specifying the name of the medicament, how imported, supplier and country of origin, date of receipt, quantity, weight or number of units imported and cost per unit to the importer after including all expenses;

(b) a register of movements of goods showing, in chronological order, the quantity in stock at the beginning of each quarter, the quantity imported, the quantity sold, the date and purchaser, and the quantity in stock at the end of the quarter;

(c) a file of all documents - properly listed in chronological order so that the Inspectorate of Pharmacy can examine them easily - relating to the amounts paid for the medicaments imported (invoices, consignment notes, bills of exchange, etc.) which will enable the Inspectorate of Pharmacy to verify the cost of every unit imported and entered in the register of goods received.

1. Examination of the documents relating to business transactions by the persons or establishments referred to in the body of this article shall be strictly private and confidential and no official notice shall be taken of such documents unless they show evidence of an offence.

2. If any establishment under inspection considers it undesirable to produce the documents required, it may appeal to the Governor of the Colony, whose decision shall be final.

3. The Inspectorate of Pharmacy shall draw up the standard forms for the registers referred to in this article.

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Article 91

In the execution of their duties the Inspectors of Pharmacy shall enjoy the following rights:

1. The right to call for assistance from the authorities or police in performing the tasks assigned to them;

2. The right of free access to all premises where trade in pharmaceutical products is carried on;

3. The right to correspond officially on service matters by post and telegraph, among themselves and with the authorities whose assistance they wish to request;

4. The right to be considered as agents of the public authorities, empowered to draw up official reports of offences detected and official acts performed, to hear and transcribe in these reports statements by offenders and third persons, to collect samples, to carry out searches and confiscations, to affix seals and to hold confiscated property in accordance with the provisions of this Order and any other relevant provisions in force.

Article 92

The administrative, health, Customs, police and other authorities on whom full enforcement of this Order may depend, shall render every assistance and give all information requested of them by the Inspectors of Pharmacy with a view to securing full compliance with the law, including the granting of access to warehouses and loading and unloading wharfs.

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Article 96

The establishments subject to supervision under the terms of this Decree are required to furnish the Inspectorate of Pharmacy with any information and explanations it may require and to permit free access to all installations at any time and to all documents requested except account books.

Article 97

Where no express provision is made for appeal procedure, appeals against application of the provisions of this Order may be lodged with the Governor of the Colony.

Article 98

Any doubts arising as to the application of this Order and any cases for which no provision is made shall be decided by the Governor of the Colony, after consulting the Council of Health and Hygiene if he sees fit to do so.

Article 99

Order of the Governor in Council No. 1:377-B of 30 December 1946 is hereby repealed.

To be published and executed as provided herein.

Residence of the Government of the Colony of Guinea, Bissau, 7 July 1948.

(Signed) Captain M. M. Sarmento Rodrigues
Governor

A

List of utensils with which pharmacies must be equipped

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B

List of drugs, chemical products and other medicinal substances, pharmaceutical preparations, whether proprietary or not, remedies for external application and accessories, the sale of which is permitted in druggists' shops and establishments with a general trading licence at places which are more than 30 km distant from the nearest private pharmacy

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C

List of Narcotic Drugs

1. Raw Opium.- "Raw Opium" means the spontaneously coagulated juice obtained from the capsules of the Papaver somniferum (L), which has only been submitted to the necessary manipulations for packing and transport, whatever its content of morphine.

2. Medicinal opium.- "Medicinal opium" means raw opium which has undergone the processes necessary to adapt it for medicinal use in accordance with the requirements of the Pharmacopoeia, whether in powder form or granulated or otherwise mixed with neutral materials.

3. Morphine, its salts and preparations.- "Morphine" means the principal alkaloid of opium having the chemical formula: $C_{17}H_{19}NO_3$.

4. Ethylmorphine or ethylmorphine hydrochloride (dionine) and other salts.- "Ethylmorphine" means the ether of morphine having the formula: $C_{17}H_{18}(OC_2H_5)NO_2$.

5. Benzylmorphine, benzylmorphine hydrochloride (peronine) and other ethers of morphine - "Benzylmorphine" means the ether of morphine having the formula: $C_{17}H_{18}(C_7H_7O)NO_2$.

6. **Benzoylmorphine,** all the other esters of morphine, their salts and preparations.- "Benzoylmorphine" means the ester of morphine having the formula: $C_{17}H_{18}(NO_2\ CO_2)\ C_6H_5$.

7. Diacetylmorphine (diamorphine, heroin), its salts and preparations.- "Diacetylmorphine" means the morphine derivative having the formula: $C_{21}H_{23}NO_5$.

8. Morphine-N-Oxide, for which genomorphine is a registered trade name, Morphine-N-Oxide derivatives and the other pentavalent nitrogen morphine derivatives.

9. Dihydromorphine, for one salt of which paramorfan is the registered name, other salts and all its preparations.- "Dihydromorphine" means the morphine derivative having the formula: $C_{17}H_{21}NO_3$.

10. Dihydromorphinone [hydromorphone][1/], dihydromorphinone hydrochloride (dilaudid), other salts and all its preparations.- "Dihydromorphinone" means the morphine derivative having the formula: $C_{17}H_{19}NO_3$.

11. Desomorphine (dihydrodesoxymorphine), and any preparations in which it is included, one such preparation being known as permonide.

1/ Note by the Secretariat: The words in square brackets have been inserted by the Secretariat. Proposed or recommended international non-proprietary names of drugs are underlined.

12. Methylmorphine (codeine) and its salts.- "Methylmorphine" means the ether of morphine having the formula: $C_{17}H_{18}(CH_3O)NO_2$.

13. Paracodeine (dihydrocodeine) - This is the codeine derivative having the formula: $C_{17}H_{19}NO(OH)(OCH_3)_2OH_2$.

14. Dihydrocodeinone /hydrocodone/, dihydrocodeinone bitartrate (dicodid), other salts and all its preparations.- "Dihydrocodeinone" means the thebaine derivative having the formula: $C_{18}H_{21}NO_3$.

15. Dihydrohydroxycodeinone /oxycodone/, dihydrohydroxycodeinone hydrochloride (eucodal), other salts and all its preparations.- "Dihydrohydroxycodeinone" means the thebaine derivative having the formula: $C_{18}H_{21}NO_4$.

16. Thebaine and its salts.- "Thebaine" means the opium alkaloid having the formula: $C_{19}H_{21}NO_3$.

17. Acetyldemethylodihydrothebaine /thebacon/, acetyldemethylodihydrothebaine hydrochloride (acedicone), other salts and all its preparations.- "Acetyldemethylodihydrothebaine" means the thebaine derivative having the formula: $C_{20}H_{23}NO_4$.

18. All the esters and ethers of the salts of the following compounds: dihydromorphine, dihydromorphinone /hydromorphone/, dihydrocodeinone /hydrocodone/, dihydrohydroxycodeinone /oxycodone/, acetyldemethylodihydrothebaine /thebacon/.

19. All preparations of methylmorphine and its salts, of ethylmorphine and of ethylmorphine hydrochloride and of other salts which contain more than 0.1 g of any of the substances when in solid preparations, such as tablets, pills and pastilles, or more than 10 per cent of the same substances in liquid preparations. Preparations of these substances in which the alkaloids are simply mixed with inert, liquid or dry substances in any proportion whatsoever.

20. Coca leaves.- "Coca leaves" means the leaves of the Erythroxylon coca (Lamarck) and the Erythroxylon novogranatense (Morris) and their varieties, belonging to the family of Erythroxylaceae and the leaves of other species of this genus from which it is possible to extract cocaine, either directly or by chemical transformation.

21. Crude cocaine.- "Crude cocaine" means any extract of the coca leaf which can be used directly or indirectly for the manufacture of cocaine.

22. Cocaine and its salts.- "Cocaine" means methyl-benzoyl laevo-ecgonine ($[\alpha]_D 20^\circ = -16^\circ 4$ in 20 per cent solution of chloroform) of which the formula is $C_{17}H_{21}NO_4$.

23. Ecgonine.- "Ecgonine" means laevo-ecgonine ($[\alpha]_D 20^\circ = -45^\circ,6$ in 5 per cent solution of water), of which the formula is $C_9H_{15}NO_3.H_2O$, and all the derivatives of laevo-ecgonine which might serve industrially for its recovery.

24. All preparations officinal and non-officinal (including the so-called anti-opium remedies) irrespective of the quantity of narcotic drugs used in them.

25. Indian hemp /cannabis/ and its galenical preparations (extract and tincture).- "Indian hemp" means the dried flowering or fruiting tops of the pistillate plant, Cannabis sativa (L). from which the resin has not been extracted, under whatever name they may be designated in commerce.

26. Hydrochlorides of p-(p-methoxyethylamine)-benzoate of p-piperidinethyl and N-methyl-4-phenyl-piperidine carbonic acid ethyl ester or 1-methyl-4-phenylpiperidine-4-carboxylic acid ethyl ester, and also the salts and preparations into which these products enter, some of these preparations being designated by the names dolantin, demerol and pethidine.

D

List of poisons

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Coca and derivatives thereof

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Opium poppies

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Pharmaceutical preparations containing toxic qualities of any of the substances listed above shall likewise be deemed to be poisons and shall accordingly be covered by this list.

Instructions for the installation of pharmacies, pharmaceutical products, laboratories, druggists' shops and any other establishments intended for the trade in, manufacture, stocking or storage of medicaments and medicinal substances

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The medicaments and medicinal substances, properly packaged, must be kept in suitable cupboards, one of them, which must be provided with a lock and key, being reserved for narcotic drugs, contraceptives, abortifacients and the poisons enumerated in List D.

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Specimen form to be used for registration of the report on the work of pharmacists' assistants to be sent to the Health Services pursuant to article 35, section 3, and also to be used for the special book which must be kept by pharmacy managers

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