Decree No. 454/976

Regulates Decree Law No. 14.294 of 10/31/974

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Regulates Decree Law No. 14.294 of 10/31/974

Montevideo, July 20, 1976.

SEEN: The need to regulate Law 14,294 of October 31, 1974 that regulates the commercialization and use of narcotics and establishes measures against illicit trade in drugs.

WHEREAS: the Special Commission appointed for that purpose has drafted the respective draft regulation.

ATTENTION: to the provisions of article 168, numeral 4º of the Constitution of the Republic,

THE PRESIDENT OF THE REPUBLIC

DECREE:

Article 1

The monopoly of the import, export and distribution of narcotic substances, contained in lists 1 and 2 of the Single Convention of 1961, ratified by Law 14,222, of July 11 , 1974, established by Law 14,294 of October 31 of 1974 and the control of its traffic with the purpose that the use of them is doneexclusively for the therapeutic needs will be exercised by the Ministry of Public Health in the following way:

A) The General Inspectorate of Chemistry, Pharmacy and Drugs, through the Department of the Comptroller of Import and Export of Narcotics, is entrusted with monitoring the application of the measures established in these Regulations.

B) The Administration Division of the Ministry of Public Health shall be responsible for taking action regarding the commercial and fiscal part of the monopoly of importation of narcotics, for which purpose it shall coordinate its management with the control over the movement of narcotic drugs that is incumbent upon it. the General Inspection of Chemistry, Pharmacy and Drugs.

Article 2

The proceeds of the legal traffic in narcotic drugs will be deposited in an account in the name of the National Commission to Combat Drug Addiction, and will be allocated to the Assistance and Rehabilitation of drug addicts, (Article 2 of Law 14,294).

Article 3

The Administration Division will report monthly to the Technical Division of the Ministry of Public Health, the movement in drug trafficking listed in lists 1 and 2 of the Single Convention of 1961, and its distribution in accordance with the power conferred by the Article 4 of the present regulation.

Article 4

The Ministry of Public Health, through the Division of Administration, will import and deliver to laboratories and drugstores that are authorized to deal with narcotics under the conditions that will be determined in the corresponding chapter of the drugs that appear in lists 1 and 2 of the Single Convention of 1961, as well as those of list 1 of the Vienna Convention of 1971.

Article 5

The Ministry of Public Health will import the drugs mentioned in article 4 when they are used in the Ministry of Public Health, or the import is requested by authorized firms.

Article 6

Diacetylmorphines (diamorphine or heroin) that are defined by chemical formula C21 H23 05N (C17 H17 C2 H3 03N), and the salts thereof will be imported by the Ministry of Public Health and issued directly by the Administration Division to pharmacies and pharmacies. authorized laboratories , with the restrictions and obligations established for the traffic of said alkaloid and its salts.

Article 7

The Ministry of Public Health will import, through the Division Administration, at the request of the drugstores and authorized laboratories, specialties containing narcotic drugs.

Article 8

The preparations containing less than 0 gr. Are exempt from the provisions of the previous article . 20 percent morphine, or less than 0 gr. 10 percent cocaine, provided that these drugs are not in solutionin an inert substance and preparations based on methylmorphine, ethylmorphine or their respective salts, which do not contain more than one gram of one or other of these substances per unit, when It is about dry preparations, granules, tablets, etc., or that

they contain more than 10% of those same substances when it comes to solutions.

Article 9

Pharmaceutical specialties that are in the conditions of exception established in the previous article, may only be imported by authorized commercial firms, which must request an authorizing certificate.

Article 10

They can trade in narcotic drugs, for the purpose of complying with professional prescriptions, without obtaining prior permission from the Ministry of Public Health and only as regards the preparation of prescriptions:

A) Pharmacists with pharmacies established and authorized by the Ministry of Public Health in accordance with the laws of April 25 , 1910 and December 27, 1937;

B) The qualified ones authorized by the aforementioned laws;

C) Physicians qualified to have a kit, according to the regulations of December 28, 1908.

Article 11

The establishments and the people who want to manufacture, manufacture, transform, use, make pharmaceutical preparations, import, export and in a general way carry out any industrial or commercial operation with the products included in these Regulations, must request a special permit from the Ministry of Health. Public

Article 12

The official, scientific or assistance institutions that want to obtain the necessary narcotic drugs for their scientific research , must also request permission to acquire them under the responsibility of their Director, indicating which drugs they will use and how much.

All clinical research with narcotic drugs and / or psychotropic drugs must be documented (with Protocol Protocol Conclusions) and registered in the Service, sending a copy to thePsychopharmaceutical Commission , which will register it in the Technical Division of the Ministry ofPublic Health, and may request timely information on the progress of this investigation.

Article 13

Specialist physicians who must use powdered cocaine hydrochloride in the exercise of their profession, as well as the medical directors of Sanatoriums, who wish to have a number of specialties withnarcotics greater than that established in these Regulations, must request the corresponding authorization.

Article 14

Permits to trade or manipulate narcotic drugs will be of different extent or importance, according to the following scale:

A) Permit to manufacture, manufacture and transform narcotics (industrial);

B) Permission to prepare preparations and pharmaceutical specialties with all the narcotic drugs and sell them only to drugstores and pharmacies (laboratories);

C) Permission to sell narcotics and specialties acquired to the Ministry of Public Health and from laboratories to pharmacies exclusively, without submitting them to manipulations (drugstores);

D) Permission to prepare pharmaceutical preparations and specialties with methylmorphine, ethylmorphine and their respective salts;

E) Permission to serve as an intermediary between the buyer and the seller (commission agent), without the existence of narcotic drugs in any form.

Article 15

To obtain permission to trade in narcotic drugs, the interested party will fill out the respective forms, which will accompany the request in which the interested party or persons will request authorization totrade in narcotic drugs, and must declare in that application that they undertake to comply with the prohibition in This Regulation and ordinance and provisions that are taken in this regard.

Article 16

Authorizations to trade in narcotic drugs will be granted with the following guarantees for the classes that are listed in article 14 of this regulation and will be in Adjustable Mortgage Obligations or in Treasury Bonds, being its acceptance subject to what the Ministry of Health resolves Public

Class A - 200 (two hundred) UR.

Class B - 140 (one hundred forty) UR.

Class C - 120 (one hundred twenty) UR.

Class D - 120 (one hundred twenty) UR.

Class E - 100 (one hundred) UR.

In its new wording given by art. 1 ° of Decree No. 80/992 of 25/2/992

Article 17

The guarantees referred to in the preceding article shall be extended by public deed, according to the formalities required by the Ministry and shall be responsible for compliance with the provisions of these Regulations.

The Ministry of Public Health may deduct, after the corresponding term, the amount of the debt owed, either as commercial transactions or as fines imposed for infractions committed.

Article 18

When the Ministry of Public Health deems it necessary, it may conveniently limit the permits to trade in narcotic drugs.

Article 19

The Ministry of Public Health may grant, deny, or withdraw at any time the authorizations to trade in narcotic drugs, without obligation of indemnities of any kind, as well as granting them, with the restrictions it deems appropriate.

Article 20

In case of withdrawal or termination of a permit, liquidation of a factory, drugstore, pharmacy, laboratory or any warehouse of pharmaceutical products , if there are narcotic products, the interested parties shall submit to the Ministry of Public Health an exact status of the stocks of such products, those that must be sealed and sealed by the General Inspectorate of Chemistry, Pharmacy and Drugs or by the official delegated by the Ministry of Public Health, who will establish where they should be deposited in custody until their destination is available .

Article 21

The settlement referred to in the previous article must be made within a period not exceeding three months, after which the products will be delivered to the Ministry of Public Health without any claim for compensation.

Article 22

In case of change of address, commercial or industrial, the holder of the permit must notify the Ministry of Public Health, before the opening of the establishment in the new premises.

Article 23

Any holder of a permit, if it sells, liquidates, changes its signature or closes its business, is obliged to give prior notice to the Ministry of Public Health .

Article 24

Permit holders are held responsible for any sale or assignment that for any reason made to persons or entities not authorized to purchase narcotics.

Article 25

The granted permission is non-transferable and will expire due to death or incapacity of its possessor, for change of signature, for transfer or liquidation of the trade.

Article 26

In the case of judicial or forced sales, the narcotic products may not be delivered to any person without complying in all its parts with the provisions of these Regulations. The delivery of the referredsubstances will be done in such cases, in the presence of a delegate of the Ministry of Public Health who will ensure that the acquirer is a person authorized for that purpose. In the event that anauthorized purchaser does not appear , said drugs will be confiscated and will be sent to the Ministry of Public Health. As soon as possible, these products will be destroyed, or if their purity or quality allows them to be used in the pharmacies of Public Health Units withoutmay, for no reason, be transferred in any way,

to authorized signatures or private pharmacies. The competent international office will be informed of this and the discharges will be established in the evaluations to be issued.

Article 27

For the acquisition of narcotics imported by the Ministry of Public Health, with the exception of heroin and its products, which shall be governed in the manner indicated in these Regulations, the followingrequirements shall be met:

A) Authorized signatures when they wish to acquire narcotics, will request the Ministry of Public Health to provide them with the quantity of drugs they require for each case, making known the origin of each narcotic drug;

B) The General Inspectorate of Chemistry, Pharmacy and Drugs will decide on the applications submitted to it for which the applicant will establish its conformity with the limitations that apply ;

C) The General Inspection of Chemistry, Pharmacies and Drugs will notify the interested party who will arrange with the respective manufacturers or their representatives, the conditions of quantity,packaging and CIF prices, of the effects whose acquisition has been authorized, communicating to the Ministry of Health Public the agreed conditions;

D) The Administration Division of the Ministry of Public Health will process the respective order directly with the manufacturer, proceeding in due time to import them;

E) The Administration Division of the Ministry of Public Health will process directly with the Central Bank the currency pertinent to the request, previously having to submit the corresponding request. In this application, the name and surname will be indicated , as well as the identity documents of the person who will take charge of those products, which from the moment of delivery will be under the responsibility of the authorized signature;

F) When the merchandise is removed, the General Inspection of Chemistry, Pharmacy and Drugs will proceed in the presence of an extractor of samples from the Office of Analysis of the Customs, to

extract three samples of each drug: one to send to the Office of Analysis of the Customs, another to be kept in your possession and the third one that you will deliver to the person who withdrew it in representation of the authorized signature.

Once the respective analysis has been verified if the good quality of the imported drugs is approved , the unused parts of the samples will be returned to the importer. The authorized signature will not beable to circulate said drugs, until the Office of Customs Analysis is issued and provided that the result of the analysis is satisfactory.

G) The Administration Division will proceed on each importation to the liquidation of the imported items. In each case, the interested parties must pay the amount of the merchandise before itswithdrawal, and pay the import expenses and Customs duties within 48 hours of the presentation of the account by the Ministry of Public Health;

H) Those interested in agreeing with the factory or representative an order of narcotic drugs, will establish that their shipment is made by air, regardless of their weight, and that the narcotic drugs aresent separately from any other product or merchandise. The shipment must be clearly identifiable and will be labeled as follows:

"Ministry of Public Health for ..... (indication of the importer) Montevideo, Oriental Republic of Uruguay.

Ar ticle 28

In the act of delivering the narcotic substances, the authorized signature must present the control book of said drugs in which the import operation shall be noted, subscribed by the official intervening in the General Inspection of Chemistry, Pharmacy and Drugs.

Article 29

A) Pharmacies and laboratories duly authorized for the sale of narcotics, will request heroin and its salts, by means of vouchers from the narcotics purchase books that will be delivered to the Supply Department and in accordance with what is established in article 11, the procedure established.

B) The quantities to be purchased may be: 2, 5, 10 Grs., Or the maximum annual supply of 20 grams.

C) The Supply Department prior to the dispatch will send all the purchase requests to the General Inspection of Chemistry, Pharmacy and Drugs , in order to verify if the petitioner did not exhaust the annual quota of diacetylmorphine in previous orders ;

D) The receipt of the merchandise must be made by the signatory (s) of the order request or by the person representing them. In this last case, the authorized signature, when formulating its request,must establish the name and surnames, as well as the series and the number of the civic credential of the person in charge of receiving the merchandise, who will prove his identity in this opportunity and will deliver an authorization extended to the effect;

E) The authorized signature must send to the Department of Supplies within the term of one month, counting from the delivery of the requested drug, a note-receipt in which it declares the date of receipt and the amount received. The non- presentation of said note, or any anomaly that may be establishedtherein , shall be brought to the attention of the General Inspectorate of Chemistry, Pharmacy and Drugs with an indication that they take the pertinent measures ;

F) The Droguería section of the Supply Department, will collect in the act of the delivery of the received merchandise and in the note- order, the written record of the conformity of the one who receives it, having, in addition, to write down the series and the number of the presented civiccredential ;

G) The Droguería section of the Supply Department will issue a numbered, tripled receipt for each sale operation, establishing:

1st) The date;

2nd) The name of the pharmacy or laboratory that you buy;

3rd) The amount of grams and totals of the product sold;

4th) The unit and total prices of the product sold;

5º) The number, the factory series of the package delivered. The original of this receipt signed by the person who

withdraws the order, will be archived. The duplicate will be delivered to the buyer and the triplicate will be attached to the settlement;

H) The Droguería section will send to the Directorate of the Supply Department , in order to be discharged into the Treasury of the Ministry of Public Health, the full amount of the sales made weekly.the references of these deliveries, will appear in the detailed liquidation, that in the first five following days of each month it will have to formulate and which will be elevated jointly with the triplicados of the receipts:

1) The Accounting Office of the Ministry of Public Health will systematically verify the accuracy of the settlement referred to in subsection H);

2) The Supply Department will inform in detail to the General Inspection of Chemistry, Pharmacy and Drugs, of the monthly sales as well as of all imported merchandise and of all imported import documents .

Article 30

Any person or establishment authorized to trade in narcotic drugs, who wish to make an exportation of these, must request the respective Ministry of Public Health each time they wish to carry out one of these operations. Said request must be accompanied by a testimony by which it is justified that theimport is duly authorized in the country of destination.

Article 31

The exportation of national specialties with narcotics, as well as their sale, must be authorized by the Ministry of Public Health, following a report from the General Inspectorate of Chemistry, Pharmacy and Drugs.

Article 32

The Ministry of Public Health will have broad powers to grant or deny these authorizations, in accordance with the provisions of these Regulations and those of international conventions. It will alsocarry a special register where the agreed permissions will be written down, by order number .

Article 33

Export certificates shall include the name and exact quantity of the product, number of containers to be shipped, net weight of each container, name and address of the recipient, name and address of theexporter and number and date of the respective import certificate and the term in which the export must be made, which may not exceed three months.

The export authorization certificate will be issued in four copies, one of which will accompany the shipment, the second will be sent to the interested party and the third will be sent to the NationalCustoms Office, which will return it to the Ministry of Public Health with the mention of the departure of merchandise from the country, once the export has been made , and the fourth will be sent to the authority in charge of the comptroller in the country of destination, in accordance with the provisions of the Single Convention of 1961.

Article 34

Bales or packagings containing any of the products included in the Single Convention of 1961 will be listed for export with the number corresponding to the respective export certificate.

Article 35

The firm that for any reason does not carry out an authorized export must return the certificate issued to the Ministry of Public Health.

Article 36

In the event that the return of a narcotic product is determined to the place of origin, the interested party must request authorization from the Ministry of Public Health giving the causes that motivate it, and will accompany the request with the testimony of the recipient country that authorizes it.

Article 37

For any shipment destined to a country that has not adopted the certificate system, the export permit will be agreed upon through the submission of a testimony from the Government of the recipientcountry , in which the circumstances for which the authorization is granted are established. interested.

Article 38

The National Directorate of Customs will not allow the entry or exit of any of the narcotic substances, or of medicines containing it, without having received the import or export certificates accompanied by a special testimony from the Ministry of Public Health , which authorizes the dispatch and those drugs.

Article 39

Once the importation or exportation has been carried out, the National Customs Office will return the respective certificates to the Ministry of Public Health, stating on the back of the same the date of dispatch, the quantity dispatched and the corresponding permit number.

Article 40

The narcotic substances included in the Conventions ratified or that are included in the future must be introduced to the country only by the Carrasco Airport and as direct cargo.

Import and export permits must be presented to the Bank of the Oriental Republic of Uruguay, which, once the operation is authorized , will be sent to the National Customs Office.

Article 41

The Customs authorities will proceed to stop all narcotic substances that are not consigned to the Ministry of Public Health, provided they are not pharmaceutical specialties that are exempted from theimport monopoly in accordance with the provisions of this Regulation. For its dispatch, a special permit from the Ministry of Public Health must be presented , which will only be issued if the importer hascomplied with the provisions of this decree. In case of detention of the merchandise, the Ministry of Public Health will be involved, which will withdraw the detained products. In the same way, any irregularity in the traffic of said substances will be checked .

Article 42

All manufacture, purchase-sale or assignment for consideration or free of charge made by any person or establishment authorized to trade in narcotic drugs and products, must be registered in a special registration book according to model approved by the Ministry of Public Health, stamped and initialed by the General Inspectorate of Chemistry, Pharmacy and Drugs. The annotations will indicate the raw materials and products purchased, date of entry, exact designation, number of materials used in the manufacture of narcotics covered by the Single Convention of 1961, quantity and nature of the products obtained by any other concept with indication of the date ofoutput, its exact designation, quantities destroyed and losses incurred in the course of manufacturing or processing, quantities used for the manufacture of products that are not covered by the Single Convention of 1961.

These inscriptions will be made by order at the time of acquisition, transfer or transformation, without amendments or interlineations. These records will always be available to the authority, which in the course of inspections should verify the registrations that have been made, and particularly ensure the use of raw materials

and manufactured products. When it comes to specialties, it must be indicated in the register, for the movement of these, their conditioning (ampoules, tubes, boxes, etc.).

Article 43

The special registry book of the comptroller of the movement of narcotics will be in the regulatory place where narcotic drugs are kept exclusively with the other documents that constitute proof of their movement (book of vouchers of acquisition, vouchers of acquisition, professional orders, etc.) and will be available at all times to the inspectors of the Ministry of Public Health . These books will conform to the model model adopted by the Ministry and it is the obligation of its owners to keep them in good condition and with thoroughness. Your pages will be listed ordinally and the General Inspection of Chemistry, Pharmacy and Drugs will make them official, giving you a number ofregistration and establishing the corporate name to be used as well as the location of the establishment, the class of permission granted, the date of registration of the book, being recorded on its first page to be signed by a technical officer of the General Inspection of Chemistry , Pharmacy and Drugs and will seal with the seal of said distribution. All the documents that prove the traffic that has been made with thenarcotic drugs and that constitute the bases of the annotations of the special book of registry, will be conserved by drug class , by species of documents and in chronological order. All these documents must be kept until the expired two years of theirdate, at least.

Article 44

Drugstores authorized to deal with narcotic drugs will be obliged to provide the Ministry of Public Health with all the reports that it may request from them regarding traffic and narcotics. Commercialfirms that do not provide the requested information or provide false reports will be subject to penalties.

Article 45

The Ministry of Public Health may withdraw the book of comptroller of narcotics for a period of no more than 10 days, as well as any other document related to the movement of said drugs. When it isconsidered appropriate, the book may be retained for more days, the authorization conferred beingsuspended in the meantime.

Article 46

The drugstores must send to the General Inspectorate of Chemistry, Pharmacy and Drugs before January 31 of each year, a state in which it will be indicated for each drug noted in the comptroller's book, these reports:

A) Existence dated January 1 of the previous year;

B) Existence with date of December 31 of the previous year;

C) Acquisitions made during the previous year;

D) Consumption during the expired year;

Article 47

Drug orders should be directed to the Ministry of Public Health and should inform the General Inspection of Chemistry, Pharmacy and Drugs if they must be accepted, modified or rejected.

Article 48

When an authorized drugstore wishes to acquire narcotics in which it has not traded the previous year, it must request that the General Inspectorate of Chemistry, Pharmacy and Drugs report on the quota that corresponds to it. The Ministry of Public Health, taking into account the existence of these drugs or other circumstances, may restrict orders.

Article 49

During the month of February of each year, the authorized drugstores will ask the Ministry of Public Health to import the drugs they need, specifying for each one of them, quantity, type of container, brand, domicile of the manufacturer, galenic formula, if it is of a preparation of that kind.

Article 50

Said order must go to the Administration Division, once the General Inspection of Chemistry, Pharmacy and Drugs has ruled favorably so that it determines the commercial conditions in which itwill take charge of the order.

Article 51

The sale price of the drugs may not exceed in more than 30% (thirty percent) the cost of acquiring them to the State (including all expenses incurred in obtaining the drug). The Ministry of Public Health may set the sale price of the drugs that it imports.

Article 52

Without prejudice to meet the import orders presented to you, the Administration Division of the Ministry of Public Health is obliged to have an existence of sufficient narcotic drugs to meet the needs of the country for a year, not having an obligation to have an existence of the specialties that areimported.

Article 53

Outside the date indicated in article 46, drugstores that wish to import narcotics, may only place new orders when their existence of drugs is less than 1/4 of the previous year's consumption. The amount that may be purchased each time, will not exceed the previous year's consumption , unless special circumstances are enforced.

Article 54

When the drugstore that wishes to acquire narcotic drugs is not interested in abiding by the provisions of article 27, the Ministry of Public Health will sell narcotic drugs of the origin and brand it has, following a report from the General Inspectorate of Chemistry, Pharmacy and Drugs.

Article 55

The drugstores and laboratories authorized to purchase narcotic drugs from the Ministry of Public Health, when selling said products to other laboratories, drugstores or authorized pharmacies, must comply with this regime:

A) All product orders will be made in special duplicate vouchers , one for ordering and one for sending, in numbered notebooks signed by the General Inspection of Chemistry, Pharmacy and Drugs.

The order voucher will remain in the possession of the retailer and the voucher will be sent filled and signed with the merchandise to the purchaser;

B) These vouchers, to be valid, must bear the seal of the pharmacy that verifies the purchase and the signature of the Technical Director of the same;

C) When a firm authorized to deal with narcotics can not fulfill an order, it must return the corresponding voucher, putting in the note the reference "can not be fulfilled".

Article 56

Authorized drugstores can only sell narcotics to pharmacies and authorized laboratories in the form in which they were acquired.

Article 57

No drugstore may sell narcotics to another, except by special authorization from the Ministry of Public Health. These sales will only be allowed after the opinion of the General Inspection of Chemistry,Pharmacy and Drugs.

Article 58

The same provisions that apply to drugstores with these exceptions will apply to laboratories :

1º Only non-specialized narcotic drugs may be acquired;

2º They can not sell simple drugs; they can only sell the preparations prepared by them and the specialties they prepare for pharmacies and drugstores.

Article 59

Before starting to prepare preparations with narcotic drugs, the laboratories will be inspected by the General Inspection of Chemistry, Pharmacy and Drugs which will require as a minimum request what is necessary within the preparations that each laboratory will elaborate, according to the request in force for pharmacies

Article 60

When a laboratory wants to elaborate a preparation or specialty that did not elaborate before, it must communicate it to the Ministry of Public Health for knowledge of the General Inspection of Chemistry, Pharmacy and Drugs.

Article 61

The laboratories must send to the Ministry of Public Health, before January 15 of each year, a list of the specialties elaborated with narcotic drugs.

Article 62

When a laboratory has to prepare its stock of preparations in the formula of diacetylmorphine, morphine, cocaine, dihydroxycodeinone or its salts, it must communicate eight days in advance the date on which it will incorporate these drugs or the drugs that must contain them, and must be present in in that case the responsible pharmacist, whose name will appear in a visible place of the establishment.

Article 63

Laboratories are obliged to destroy the containers that contained the products listed in lists 1 and 2 of the Single Convention of 1961.

Article 64

Narcotic drugs and derived preparations shall be packed , as soon as possible, and labeled with labels that contain, in a clearly readable form, the indications relating to their quality, quantity, name and address of the vendor, numbering of progressive series in such a way that facilitate your identification at any time.

The galenic products of the specialties for sale must have a visible label to the public with the indication of the dose of the narcotic substances or substances contained in one hundred parts of itscomposition, having to keep in its container a control number that allows to follow the identification of the unit. the circulation of preparations covered by this Regulation will not be allowed , without thecorresponding authorization to sell by the Ministry of Public Health.

It must be expressed in the container, in thick characters, which can only be sold under the specialty professional recipe. Without these indications, the substances included in these Regulations may not be circulated or imported, exported or possessed.

Article 65

Losses in the course of manufacturing or processing (normal losses) will be recorded in the special registration book and will be discharged by the inspectors of the Ministry of Public Health, if in theiropinion the deficit is the one that normally results from the transformations or manipulations declared.

The loss resulting from a spill, theft or any other similar accident (accidental losses) must be reported to the General Inspectorate of Chemistry, Pharmacy and Drugs, or to the delegates of the Ministry of Public Health, within twenty-four hours. known the fact.

Article 66

Specialties for professionals who can prescribe narcotics will be subject to the following regime:

A) It will be kept in the book of comptroller of narcotics, an item destined to each specialty from which originals are delivered;

B) It will be carried out with each specialty dedicated to samples, the same control as for any narcotic drug;

C) The professional to whom the specialties will be destined must sign two receipts, in the case of recipes requiring duplicate, which will include the name and surname, profession and address of the professional. One of the receipts will be kept by the supplier of the specialties as proof of the departure of these, and the other will be sent to the Chemistry, Pharmacy and Drug Inspection on the date that it determines for the reception of the duplicates of the recipes;

D) Specialties may be delivered, also at the request of the doctors who have the right to use them when they request it in the prescriptions provided by the Ministry of Public Health.

Article 67

No pharmacy will be able to deliver narcotics, except by prescription from a doctor, dentist or veterinarian, which must be in accordance with the limitations established in this Regulation.

Article 68

The pharmacists will keep, for at least two years, the recipes that justify the movement of the control book in accordance with the provisions of Article 42 of these Regulations.

Article 69

The pharmacists are obliged to record in the book of control of narcotics, the entrances and exits that take place, having to fulfill exactly the arranged thing in the article 42.

Article 70

When the doctor has omitted the name and address of the patient and this was known to the pharmacist, you must register it in the prescription, making sure that the medication is delivered to theaddress that you have entered in the prescription that you must sign.

Article 71

The recipes containing the products of lists 1 and 2 of the Single Convention of 1961, whether in master formulas or pharmaceutical specialties , must be prescribed in the prescriptions provided by the Ministry of Public Health for such purposes, not being able to be dispatched by the pharmacies those recipes, when that requirement is omitted. In case of evident urgency, a duplicate common prescription may be issued, and in this case, the patient's identity document must be attached, and the copy of the prescription must be sent to the General Inspectorate of Chemistry, Pharmacy and Drugs, with the pertinent declaration.

Article 72

The duplicate will not only contain the prescribed formula, but also all the data related to the patient, required by this Regulation:

names and surnames, residence of the patient, and will be sent to the General Inspectorate of Chemistry, Pharmacy and Drugs, within the first ten days of the month following that of his office.

Article 73

In the case of a sick person who has a Ministry of Public Health card , instead of the address, the card number and identity document can be registered .

Article 74

The recipes of the ophthalmologists in whom Cocaine Hydrochloride is prescribed with other active substances in the usual form and dose for eye drops (less than 2 percent) will not need duplicate .

Article 75

Pharmacists who do not send, within the statutory period to the General Inspection of Chemistry, Pharmacy and Drugs, all the duplicates of prescriptions duly sealed and numbered, will be subject to sanctions.

Article 76

When a pharmacy does not ship any narcotic drugs included in these Regulations during a month, it must notify it within the term established for the General Inspection of Chemistry, Pharmacy and Drugs. Pharmacies must destroy original empty containers that have contained products from lists 1 and 2 of the Single Convention of 1961.

Article 77

For their acquisitions in drugstores and laboratories, and in regard to stocks of narcotic drugs, pharmacies strictly adhere to the provisions of the articles of this regulation. Without special authorization for this, pharmacies may not sell, transfer or deliver in exchange or in any other waynarcotic substances .

Article 78

When a doctor prescribes higher doses than allowed, according to the provisions of the following articles, the pharmacist can only send them when the doctor signs the original and duplicated in the respective recipe and write it down in his own handwriting. "special case", and the patient's identity document.

Article 79

The maximum amount of each narcotic that can be prescribed in a prescription will not exceed ten daily doses.

Article 80

In case of exception, the professional may prescribe on papers that do not have their professional letterhead, in this case having to write their name and surname, profession and address and identity document, in the paper that is prescribed, both in the original and in the duplicate , in perfectly legibleform .

Article 81

The Ministry of Public Health may require doctors to prescribe doses in excess of the regulations for "special cases " that state the reason for doing so.

Article 82

When there is suspicion that a professional makes illegitimate use of their professional rights, the background will be raised to the Minister of Public Health, so that he can submit the case to the Public Health Commission, in accordance with the duties established by the Law. Organic Public Health 9,202 of January 12, 1934.

Article 83

For the purposes of the application of the provisions of these Regulations, maximum doses established in the Official Pharmacopoeias are declared.

Article 84

Physicians who are directors of sanatoriums who wish to prescribe narcotic drugs in solution or in a specialized manner in doses higher than those regulated, must request authorization from the Ministry of Public Health.

Article 85

In the event that the Ministry agrees to the request referred to in the preceding article, it will provide said doctors with a procurement book similar to that used by the pharmacies, in which the following will be written in all its pages: "Sanatorium" . With these vouchers you can buy up to 10 specialized formulas or 50 maximum daily doses of each medicine already prepared.

Article 86

The directors of sanatoriums who take advantage of this prerogative may not retain in their possession, for the use of the sanitarium, a stock greater than 10 specialized formulas or 50 maximum doses of each medication.

Article 87

The directors of sanatoriums who avail themselves of the prerogative conferred by article 84, must register in a control book, date, amount administered and name of the patient to whom it was administered and the data required in article 42.

Article 88

Both the registration book mentioned in the previous article and the purchase book and the narcotics must be kept in a closet in the conditions required in article 43.

Article 89

When a pharmacist has doubts about the authenticity of the signature of a prescription or the quality of professional qualified to formulate it, it will obtain reports from the General Inspectorate of Chemistry,Pharmacy and Drugs, if it is installed in the Capital, and if it is in the interior, to the Center of Public Health of the locality.

Article 90

Individuals may only have in their possession narcotics when there is an optional prescription for this, which will be demonstrated with the copy of the respective prescription, which must be issued by the pharmacy that produces it, or with the justification inscribed in the prescription of the same Allow to establish the number of the recipe that will be written on the label of the medicine container.

Article 91

The General Inspection of Chemistry, Pharmacy and Drugs, will make monthly the study of the duplicates of the prescriptions with narcotics established by the article 71, giving account of

its result to the National Commission of Fight against Drug Addiction, which will communicate the result of that I study the doctors who in the month have prescribed more than 50 maximum doses.

You may also request from the doctor the reports that you think are useful.

Article 92

When a doctor suspects that there are falsified or modified prescriptions of his , he must inform the General Inspectorate of Chemistry, Pharmacy and Drugs as well as any report on possible misuse of narcotics.

Article 93

When the inspectors verify in an inspection, the presence of drugs in poor condition, will proceed to seal the containers that contain them that can not be used until they are analyzed by the Chemistry Laboratory of the Ministry of Public Health and the latter determines that those drugs are able to be used. If said laboratory determines that these drugs do not meet the necessary conditions to be official, they will be destroyed.

Article 94

The Ministry of Public Health will provide the Inspectors with a card that will include: names, surnames, photograph, identity document and position of the official. In said card the article corresponding to Law 14,294 will be transcribed .

Article 95

The sale or delivery to the public of the pharmaceutical specialties that due to its formula of composition and dose of its components have psychopharmacological action , will be carried out only after presentation of a professional prescription .

Article 96

All recipes must be with the name and address of the professional. The firm signature will appear at the foot.

Article 97

The recipes of the Collective Medical Assistance Institutions will be made in duplicate. The word "Duplicate" should appear in the recipe.

Article 98

Professionals may only prescribe one unit per prescription. In the event of an exception, medical professionals may prescribe more units, with the names and surnames, address and identity document in the prescription .

Article 99

The recipes to obtain the originals referred to in article 11, subsection 2 of Law 14,294, will be made in duplicate and the Laboratory will send the original to the General Inspectorate of Chemistry, Pharmacy and Drugs together with the monthly movement of psychotropic drugs .

Article 100

The containers of said pharmaceutical specialties must carry on their labels, containers and leaflets, the legend "Controlled Drug", written with letters of the same size as the letters of the name of thespecialty and, in color that contrasts with the container, label and leaflet .

Article 101

The psychotropic drugs will be released for public use only in original containers , whose content will not be less than 10 (ten) tablets or more than 100 (one hundred) tablets, 15 (fifteen) cc. of solution, 100 (one hundred) cc. of suspension, 10 (ten) ampoules or 6 (six) suppositories. The sample is forbidden for professional propaganda (free sample).

Article 102

It authorizes the sale by laboratories in containers of greater quantity, individualizing the tablets with the name and dose, to the Hospital of Clinics, Military Health, Police Health and Ministry of Public Health.

Article 103

To the Healthcare Centers authorized by the Ministry of Public Health to possess stock of medicines, the laboratories may sell them in special (economic) containers, with the same amounts established in article 101, which may not be divided.

Article 104

Propaganda of the specialties included in article 95 may only be carried out with the authorization of the Ministry of Public Health, through the intermediary of the Honorary Commission of the Comptroller of Medicines, with prior approval of the Psycho-drug Commission. In no case will it have popular dissemination. The prospect in the packaging of psychopharmacological action specialties, to avoid popular dissemination of their actions should not contain neither these nor the indications, but the posology and contraindications.

Article 105

The Ministry of Public Health, through the General Inspection of Chemistry, Pharmacy and Drugs of the Technical Division, will control the availability and use of the raw material for the preparation ofpharmaceutical specialties with psychopharmacological action, as well as the distribution and sale of the same. For such purposes, the traffic of said raw material must be previously authorized by the General Inspectorate of Chemistry, Pharmacy and Drugs, which will issue the corresponding export and import certificate .

Article 106

The psychotropic drugs may be released to the public only by the establishments authorized for this purpose (private pharmacies, hospital pharmacies and authorized medication dispatches), which shall proceed as follows:

A) They will demand the delivery of the professional recipe;

B) They will place the recipe in the Pharmacy's Recipe Book and they will stamp on the same date, stamp of the Pharmacy and number that corresponded to it in the Receipt Book. In case of sale of drugs, it will be done under a medical prescription, it will be copied in the corresponding Receipt Bookand it will be completed. The Collective Medical Assistance Institutions, when they dispatch psychotropic drugs, will carry daily movement cards of psychotropic drugs, and weekly they will record the result in the corresponding Receipt Book.

Literal B) in its new wording given by art. 1 ° of Decree No. 95/988 of 26/1/988

C) Monthly plan in duplicate the sale of psychotropic drugs and drug movements;

D) Importers, representatives, suppliers of medicines will carry a similar form, discriminating the sales made.

The original of the template will be for two years in the establishment together with the prescriptions or invoices dispatched during the month. The forms will be sent to the General Inspectorate of Chemistry, Pharmacy and Drugs between the 1st and 10th of the following month, endorsed by the responsiblePharmaceutical

Chemist . The original will remain in the office and the sealed and signed copy will be returned to the interested party for filing.

Article 107

The authorization for donations of psychotropic drugs to the institutions authorized by the Ministry of Public Health must be previously managed by the donor before the Psychopharmaceutical Commission, attaching the request of the recipient. Donations will be subject to the provisions of article No. 106.

Article 108

All clinical research with psychotropic drugs must be documented (with Protocol Program, Conclusions) and registered in the Service , sending a copy to the Psychopharmaceutical Commission that will register it in the Technical Division of the Ministry of Public Health and may request timely information on the march of said investigation.

Article 109

The Executive Power on the initiative of the Ministry of Public Health will determine the psychotropic drugs (drugs and pharmaceutical specialties), whose traffic is regulated, integrating them in the list for the knowledge of the interested parties. This list will be reviewed every six months by the Ministry of Public Health, for the purpose of updating it by the Executive Branch and publicizing it.

Article 110

The Ministry of Public Health, through its competent offices, will monitor compliance with the provisions contained in this decree and will apply the corresponding sanctions, in accordance with the regulations in force, which may result in the closure of infringing services, institutions or establishments. These sanctions include the professionals responsible for prescribed prescriptions.

Article 111

The circulation in transit throughout the national territory of narcotic or psychopharmacological substances from and destined abroad is expressly prohibited .

Article 112

Create a Special Commission integrated with representatives of the Ministry of Public Health and the National Directorate of Customs with the task of coordinating the nomenclatures between the two organizations in relation to drugs, in order to adjust the corresponding controls.

Article 113

Repeal all provisions that are contrary to these Regulations, especially decrees 577/973 of July 17, 1973 and 77/974 of January 29, 1974.

Article 114

Communicate, publish, etc.

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