

# **Decree No. 288-96, establishing the Regulation of Law 50-88 on Drugs and Controlled Substances of the Dominican Republic**

**JOAQUIN BALAGUER**

**President of the Dominican Republic**

NUMBER: 288-96

WHEREAS: The legal instrument amending Law 50-88 of 30 May 1988 1) containing provisions to prosecute and punish the laundering of assets obtained from and/or connected to illicit traffic in drugs and controlled substances in the Dominican Republic, stipulates in its final article no. 116 (transitional) that for the purpose of its entry into force it is necessary to enact the implementing Regulation specified in article 94 of Law 50-88

BEARING IN MIND Law 50-88 of 30 May 1988, on Drugs and Controlled Substances in the Dominican Republic, and Law No. 17-95, of 17 December 1995, (2), which amends it.

BEARING IN MIND the United Nations Convention against Illicit Trafficking in Narcotic Drugs and Psychotropic Substances, signed at Vienna, Austria, on 20 December 1988, ratified by the National Congress and promulgated by the Executive on 23 June 1993.

In exercise of the functions conferred on me by paragraph 2 of Article 55 of the Constitution of the Republic,

**I DECREE AS FOLLOWS,**

**Article 1.**

The Regulation of which the text follows is adopted.

**REGULATION OF LAW 50-88 ON DRUGS AND CONTROLLED SUBSTANCES OF THE DOMINICAN REPUBLIC**

**CHAPTER 1 GENERAL PROVISIONS**

This Regulation shall be known and may be cited as Regulation No. 1 on Drugs and Controlled Substances".

**ARTICLE No. 1.**

The purpose of this Regulation is to regulate action to combat and eradicate the production, supply and illicit traffic and unwarranted use of Drugs and Controlled Substances in the Dominican Republic, and to establish the necessary standards and procedures to control the manufacture and dispensing of drugs and controlled substances, and to fix reasonable duties

payable for the registration required under Law 50-88 on Drugs and Controlled Substances of the Dominican Republic, and its amendments.

## **ARTICLE 2. - DEFINITIONS**

Except where otherwise specified, the following definitions will apply exclusively to the entire text of the following Regulation:

1. Goods" means assets of any kind, whether corporeal or incorporeal, movable or immovable, tangible or intangible, and the legal documents or instruments confirming ownership and other rights to such assets;
2. Basic Category" refers to the substances listed in Articles 8 and 38 of Law 50-88;
3. Confiscation" means the final removal of any item of property by the decision of a court;
4. Director" means the Director of the National Drug Control Directorate;
5. Director" means the Director of the Division of Drugs and Pharmacies of the Ministry of Health and Social Welfare, in coordination with the National Drug Control Directorate;
6. Dispensing agent" means the professional (doctor, veterinary surgeon, dentist or pharmacist) authorized according to a register issued by the Director to dispense controlled substances. The dispensing agent may be confined by the register to one or more of the following activities:
  1. Carrying out investigations;
  2. Carrying out chemical analysis;
  3. Carrying out educational activities;
  4. Prescribing;
  5. Administering;
  6. Preparing and dispatching for delivery to the end consumer;
7. Institutional Dispenser" means any hospital facility, clinic, dispensary, centre or public or private institution offering medical and/or hospital services, which is properly licensed by the Ministry of Public Health and Social Welfare;
8. Related offences" means the actions or activities specified in Articles 99, 100 and 101 of Law 50-88 and its amendments;
9. Commercial container" means a flask, capsule, tube, ampoule or other container containing controlled substances for distribution or dispensing. The term refers directly to the substance, not to the packaging;
10. Pharmacy" means an establishment authorized and registered with the Ministry of Health and Social Welfare, which is also authorized on a register issued by the Director to dispense controlled substances to the end consumer;
11. Pharmacist" means a professional licensed by the Executive by means of an exequatur;
12. Manufacturer" means the person authorized to manufacture a drug or a controlled substance;
13. Manufacture" means the production, preparation, reproduction, making or elaboration of a drug or other controlled substance, whether directly or indirectly or by extraction from substances of natural origin, or independently by means of chemical synthesis, or by the combination of extraction and chemical synthesis, and including any packaging or repackaging of such substance or the labelling of its container;
14. Controller" means an official or employee of the section who has been appointed by the National Drug Control Directorate (DNCD);
15. Seizure" means the temporary custody or control of goods under a warrant issued by a court or by the National Drug Control Directorate, after fulfilling the appropriate legal requirements;
16. Instrument" means the objects used or intended for use for the purpose of committing the offence of illicit traffic or related offences;
17. Importer" means any person in the Dominican Republic who imports or is an agent for importing drugs and controlled substances;
18. Importation" means the bringing in of controlled substances into the Dominican Republic

- by any lawful method, from any part of the world;
19. Isomer" means an optical isomer;
  20. Research" means study and medical, scientific or pre-clinical experiments, and the chemical analysis of controlled substances carried out by persons holding a certificate issued by the Director of the Division of Drugs and Pharmacies of the Ministry of Public Health and Social Welfare and/or the National Drug Control Directorate;
  21. Law" means Law 50-88 on Drugs and Controlled Substances of the Dominican Republic, and its amendments;
  22. Supervised premises" means a) a place in which the records, stamps, certificates and other original documents in accordance with this Law and this Regulation are kept, b) a place, including factories, stores and other establishments or means of transport where persons registered under the Law may legally hold, manufacture, distribute, dispense, administer or in any other manner dispose of controlled substances;
  23. Name" means the specific chemical designation or the official, ordinary or customary name or trade name of a controlled substance;
  24. Examining Official" means the official appointed by the Director of the National Drug Control Directorate;
  25. Person" means all natural or legal entities able to acquire rights or contract obligations, such as a corporation, a joint company, a trustee, an estate, a limited company, an association, a joint venture or other entity or group whether or not it is registered as a civil or commercial company;
  26. Product" means the goods obtained or derived directly or indirectly from the commission of an offence of illicit traffic or related offences;
  27. Property" means goods subject to confiscation or to any act of retention under law;
  28. Professional" means a doctor, dentist, veterinary surgeon, scientific researcher, pharmacist, pharmacy, hospital, or other person with a registered licence or a licence in a form authorized by the Dominican Republic for distributing, dispensing, carrying out experiments or administering or using for teaching purposes or in chemical analysis a controlled substance in the course of his practice or professional research in the Dominican Republic;
  29. Individual professional" means the doctor, dentist or veterinary surgeon who is authorized by a register issued by the Director to dispense controlled substances in the course of his professional practice in the Dominican Republic. This does not include a pharmacist, a pharmacy or a professional institution;
  30. Professional institution" means a hospital or institution with a licence, authorized by a register issued by the Director to dispense controlled substances. The term "professional institution" does not include pharmacies;
  31. A person having suffered loss" means any person adversely affected by any regulation, order, resolution or action of the Director of the Division of Drugs and Pharmacies of the Ministry of Public Health and Social Welfare and/or the National Drug Control Directorate;
  32. Register and Regulation" refers solely to the registration certificate which is required and permitted by law and which is proposed in this Regulation;
  33. Registered subject" means any person who is registered in accordance with the Law and its Regulations;
  34. Tag or label" means any piece of written or printed material placed on the commercial container of a controlled substance by the manufacturer or by the dispensing agent;
  35. Registration" means the Class A certificate issued by the National Drug Control Directorate through the Division of Drugs and Pharmacies, giving doctors, dentists and veterinary surgeons the right to prescribe or administer controlled drugs. It lasts for three years from the date of issue. The "annual" Class B certificate issued by the National Drug Control Directorate through the Division of Drugs and Pharmacies authorizes manufacture, distribution, dispensing or research concerning controlled substances. "Re-registration" means the registration certificate which is issued when the original expires;
  36. Illicit traffic" means the offences listed in Law 50-88 on Drugs and Controlled Substances in the Dominican Republic and its amendments, dated 30 May 1988.

### **ARTICLE 3. - FUNDAMENTAL PRINCIPLES**

1. The National Drug Control Directorate, as a specialist institution, in accordance with the norms established in Law 50-88 on Drugs and Controlled Substances of the Dominican Republic and its amendments, is essentially a subordinate, non-political body, and has no authority to make decisions of its own in any circumstances.
2. The purpose of establishing the National Drug Control Directorate is specifically defined in article no. 10 of the Law 50-88 on Drugs and Controlled Substances of the Dominican Republic and its amendments.
3. The National Drug Control Directorate is governed strictly by the provisions of Law 50-88 on Drugs and Controlled Substances in the Dominican Republic and its amendments, as by the provisions of the Constitution of the Republic and the laws and regulations referring to it.

### **ARTICLE 4. - THE MEMBERS**

1. To be a member of the National Drug Control Directorate, in addition to the requirements listed in Articles 12 and 13 of Law 50-88 on Drugs and Controlled Substances in the Dominican Republic, the following are required:
  1. To be a Dominican citizen, man or woman, in full enjoyment of his or her civil and political rights;
  2. To have completed his or her eighteenth (18) year;
  3. To hold a bachelor's degree, attested by the appropriate certificate, which must be attached to the record of admission, except in the case of domestic and cleaning staff;
  4. To be in good physical and mental health, as certified by a medical examination;
  5. To be of good character and to submit a clean police record from the Prosecutor's Office of the place of residence and from the police;
  6. Not to have been convicted of any crime or offence, nor to have been debarred from another public service for misconduct;
  7. Not to have pending any public proceedings.

### **ARTICLE 5. - CATEGORIES**

1. The category or categories in which a person or persons trading illicitly in drugs and controlled substances is placed, will depend on the quantity and type of the drug or controlled substance which is seized from the subject, the determination being based on weighing instruments, either a kilogram weight or a weighing scales..
2. EQUIVALENTS,
  1. One (1) gramme is equivalent to one thousand (1000) milligrammes;
  2. One (1) pound is equivalent to four hundred and fifty four (454) grammes;
  3. One (1) ounce is equivalent to twenty-eight point thirty eight (28.38) grammes;
  4. One (1) kilo is equivalent to one thousand (1000) grammes;
  5. One (1) kilo is equivalent to two point two (2.2) pounds;
  6. One (1) tonne is equivalent to two thousand (2000) pounds.

In the case of any other hallucogenic substance, or in the case of opium and its derivatives in any quantity, the person or persons indicted for trafficking will be classified on the basis of Article 7 of Law 50-88 on Drugs and Controlled Substances in the Dominican Republic, and its amendments.

### **ARTICLE 6. PROTOCOL ON ANALYSIS AND CUSTODY PROCEDURE**

1. In the event of seizure by the authorities of drugs and controlled substances to which Articles 5, 6, 7, 8 and 9 of Law 50-88 on Drugs and Controlled Substances in the Dominican Republic refers, and where appropriate of the raw materials used to make them, a quantity which is technically sufficient for the purpose will be separated from them and immediately handed over to a forensic laboratory in which the necessary expertise is available.
2. The forensic laboratory must analyse the sample of the substance sent to it within not more than twenty-four (24) hours, and within this period must issue an analysis report identifying the substance and its characteristics, which shall specify the quantity, weight, name, quality and class or type of substances to which the law refers, and the number assigned to the analysis, the department requesting it, the official making the request, the department to which the requesting official belongs, the description of the person or persons from whom the substance has been seized, a description of the evidence and the results.
3. Where there are special circumstances warranting it, this period may be extended by twenty-four (24) hours, at the request of the officials who have seized the controlled substances in question.

This analysis must be carried out in the presence of a member of the Public Ministry, who shall sign the original and the copies, failing which it will be void.

4. The investigating officials will ascertain whether the substance sent to them constitutes a drug or a controlled substance, and if this is the case will immediately submit the analysis report to the Legal Department of the National Drug Control Directorate for the purpose of preparing a file and instituting legal proceedings.
5. The analysis report will have evidentiary value in accordance with the provisions laid down in articles 87 to 90 of the Dominican Code of Criminal Procedure.
6. Following the analysis to which the third paragraph of this article refers, the drugs and controlled substances must be burnt in accordance with Law 50-88 on Drugs and Controlled Substances in the Dominican Republic and its amendments. A record will be made of the administrative procedure of burning or destruction, and a copy of the record must be sent to the competent court no later than ten (10) days after it has been made.

## **ARTICLE 7. - ADMINISTRATION, CONTROL, SEIZURE AND TRANSMISSION OF SEIZED ITEMS**

1. Movable and immovable property, instruments, equipment and other objects used in committing the offences defined in Law 50-88 on Drugs and Controlled Substances in the Dominican Republic and its amendments, which have been seized under Articles 33, 34 and 35 of Law 50-88 on Drugs and Controlled Substances in the Dominican Republic and its amendments, and the various items of property and assets derived from such activities, shall be administered by the National Drug Control Directorate, in conformity with Article 10 e) of that Law, until a final and irrevocable confiscation order is made against them.
2. When the seized items require maintenance, the National Drug Control Directorate is authorized to use them, until the case is finally settled in the courts. When necessary, the National Drug Control Directorate must insure the seized items, in order to guarantee replacement in the event of damage or destruction.
3. In the case of money, the National Drug Control Directorate shall deposit it in a current account in a bank belonging to the national banking system, previously approved by the Comptroller General of the Republic. The Governing Board of the National Drug Control Directorate may authorize the opening of fixed term deposit certificates, and the interest will be used for its purposes.

4. Where registered immovables are seized, the competent court shall immediately order an entry to that effect on the reverse of the title certificate in the appropriate Register of Titles, and shall notify the National Drug Control Directorate.
5. The National Drug Council shall be responsible for ensuring due implementation, in cases of confiscation, of final and irrevocable judgments handed down by the competent courts.
6. If the movable and immovable goods, instruments, equipment and other objects used in committing the offences covered in Law 50-88 on Drugs and Controlled Substances of the Dominican Republic and its amendments are not the property of those involved, they shall be returned to their lawful owners, provided it can be shown that no liability was incurred. Restoration shall also be made of goods ordered to be returned by the competent court by means of a final judgment having the force of *res judicata*.
7. The procedure for requesting the return of the goods described in paragraph 6 shall be as follows:
  1. The person concerned or his legally authorized representative must make a request for restitution in writing, giving the reasons, and send it to the National Drug Control Director; and
  2. Must attach copies of the documents attesting ownership.
8. Commercial vessels, whether aircraft or land vehicles or ships, in which drugs are found in luggage under the passenger's sole responsibility, shall be exempt from confiscation or seizure. However, means of transport  
  
for registered cargo must require a sworn declaration of its contents. Rural and urban estates on which drugs are found shall also be exempt from confiscation and seizure, provided the owner is able to prove he is not responsible.
9. If the court orders the confiscation of the goods referred to above, by means of a final and irrevocable order, they must be handed over to the National Drugs Council for disposal according to Article 76 of Law 50-88 on Drugs and Controlled Substances of the Dominican Republic and its amendments.

## **ARTICLE 8. - SEARCHES**

1. The involvement of members of the National Drug Control Directorate in searches of homes, public places and any means of transport (ships, aircraft, cars, etc.) shall comply with the following procedure:
  1. The members of the National Drug Control Directorate must always be accompanied by a Prosecutor's Assistant or by a Public Prosecutor in searches of homes, public places or any kind of transport, whether cars, aircraft or ships. The search will be directed by the representative of the Public Ministry;
  2. The Prosecutor must hold proper authorization in writing from the Public Prosecutor or the Attorney General of the Republic in order to make any search between six (6) in the evening and six (6) in the morning of the next day;
  3. It is forbidden to inspect or search any of the above-mentioned places unless done by a representative of the Public Ministry;
  4. The person responsible for the search must use his judgment in order to determine the number of assistants needed to accompany him in the search procedures. The other staff will be deployed to ensure safety in the vicinity of the houses, public places and means of transport;
  5. The person responsible for the search must always be accompanied by a member of the family residing in the house, an employee of the public place or a crew member in the case of ships or aircraft, in each of the various areas when they are being searched. The remainder of the family, staff or crew must be kept apart and in safety;

6. The person responsible for the search must read the search record and ascertain that it is complete and correct before affixing his signature to the document;
7. The person responsible for the search must promptly display his identification document, in a courteous and correct manner, when presenting himself at a private house, public place, ship or aircraft for the purpose of a search;
8. Before carrying out a search the members of the National Drug Control Directorate must have sufficient indication that the place is connected with drug trafficking, through prior investigation;
9. Goods, objects and documents seized during the search must be properly detailed in the record of the search, which will be drawn up by the representative of the Public Ministry; the items concerned will remain in his care and custody, in accordance with Articles 32 to 40 of the Dominican Code of Criminal Procedure;
10. If the person responsible for the search finds nobody in the premises searched, or finds the premises locked, he shall proceed according to Articles 32 to 40 of the Dominican Code of Criminal Procedure.

## **ARTICLE 9. - SPECIAL PROVISIONS**

1. In addition to the prohibitions laid down in Articles 86 and 87 of Law 50-88 on Drugs and Controlled Substances of the Dominican Republic and its amendments, those guilty of breaching the provisions of that Law shall not be granted pardon, release or exemption from fines.
2. When the National Drug Control Directorate acts in a case of illicit traffic *in flagrante* in drugs and controlled substances, committed by using airports or landing strips under private ownership, he may occupy them, and their operating licence will be cancelled by the competent authority either temporarily or permanently, according to the extent of participation by their owner in the commission of the offence.
3. The same sanction will apply to the proprietor, lessee, administrator or holder under any title of an immovable or establishment which is used to consume, prepare, store or distribute illicit drugs, or which is made available to another person in the knowledge that it is being or will be used for such activities.
4. In the case of commercial premises or places of public entertainment, the premises will be finally closed if it is shown that their proprietors or administrators intended them for the purpose of the conduct referred to in paragraph 2.
5. The same sanction will be imposed if it is established that these premises or entertainment centres have repeatedly been used for the purpose of the offences covered in Law 50-88 on Drugs and Controlled Substances of the Dominican Republic and its amendments, even if the proprietors or administrators did not participate in committing the offences.

## **CHAPTER II GENERAL PROVISIONS FOR THE CHEMICALS AND PRECURSORS SECTION**

### **ARTICLE 1. - FUNCTIONS OF THE CHEMICALS AND PRECURSORS SECTION**

The Director of the National Drug Control Directorate may delegate to the head of the Chemicals and Precursors Section of the Directorate, who may in turn sub-delegate to the controllers, functions relating to the performance of his duties and the exercise of his powers under Law 50-88, Articles 24 and 25, and this Regulation.

### **ARTICLE 2. - DIRECTOR'S AUTHORITY TO ISSUE CERTIFICATES**

The Director shall issue certificates authorizing the manufacture, distribution and/or dispensing of controlled substances in accordance with this Regulation.

### **ARTICLE 3. - AUTHORITY TO ACT**

No person may take part in activities for which a certificate is required, until his request for a certificate has been approved and it has been granted to him.

### **ARTICLE 4. - WHO MUST REGISTER**

The following must obtain an annual registration certificate in accordance with this Regulation:

1. Any person engaging in or wishing to engage in the manufacture, distribution or dispensing of any controlled substance, unless exempted from this requirement by Law 50-88 or by this Regulation. Only persons engaged in and participating directly in such activities must register, not persons connected or associated with them who do not engage in or take part in such activities.
2. The laboratories of the Division of Drugs and Pharmacies carrying out chemical analysis, not constituting field tests, and other preliminary chemical tests made by staff exempt from registration.
3. Any seagoing vessel and any aircraft duly registered for air traffic which holds office in the Dominican Republic to dispense and keep controlled substances on board.

Certificate holders, in conformity with Law 50-88 and this Regulation, shall submit a report to the Division of Drugs and Pharmacies by 31 December on the controlled substances acquired in the Dominican Republic, the amounts dispensed and the balance held on that date.

### **ARTICLE 5. - PERSONS EXEMPT FROM REGISTRATION**

The following are exempt from the requirement to obtain a registration certificate:

1. All persons exempted and/or exonerated by Law 50-88 or this Regulation.
2. Any seagoing vessel engaging in international trade, or any commercial aircraft duly registered for civil aviation which has no office in the Dominican Republic, if the controlled substances kept on board have been acquired to be kept and dispensed under the supervision of:
  1. A doctor licensed in the Dominican Republic;
  2. A duly accredited medical official;
  3. The captain of the vessel or the pilot of the commercial aircraft, as applicable, if the vessel does not employ any doctor licensed in the Dominican Republic.

When a seagoing vessel or commercial aircraft without an office in the Dominican Republic is in need of controlled substances, the doctor licensed in the Dominican Republic, the duly accredited medical official, the captain or the pilot, as appropriate, will acquire the controlled substances having first obtained authorization from the National Drug Control Directorate, to be submitted to the Division of Drugs and Pharmacies, which shall issue a "Class B" certificate permitting acquisition of the controlled substances from a distributor registered in the Dominican Republic.



3. An individual professional, whether an intern or resident doctor, an external qualified doctor or a doctor of a medical faculty of a recognized university, who is employed by a hospital or other registered institution.

This individual professional may dispense (prescribe) controlled substances under the registration certificate of the hospital or institution for which he works, without having to be registered, provided that:

1. The dispensing (prescribing, administering) is done in the usual course of his professional practice within the hospital or other registered institution;
  2. The individual professional is authorized to practise his profession in the Dominican Republic;
  3. The hospital or other institution employing him has ascertained that the individual professional is qualified to dispense (prescribe, administer) controlled substances in the Dominican Republic;
  4. The hospital or other institution will give permission to the individual professional to dispense (prescribe or administer) under the registration certificate of the hospital or institution, and will give each individual professional a special internal code number. The code number will take the form of a number or letters, or a combination of both, and will form a suffix to the registration number of the hospital or institution, preceded by a hyphen. Responsibility for professional qualifications and moral suitability lies with the hospital or institution;
  5. The hospital or other institution shall maintain an up to date list of the internal codes, with the names of the corresponding individual professionals. This list shall be available at all times for inspection by the Division of Drugs and Pharmacies, and may be requested by another registered subject or by the National Drug Control Directorate, which shall ensure compliance with Law 50-88 for the purpose of verifying the authority of the individual prescribing professional.
4. Any doctor practising in the Army, the Air Force, the Navy or the police who is authorized to dispense (prescribe or administer, but not request or buy) controlled substances in the course of his official duties. These officials shall follow the procedures laid down in this Regulation with regard to prescriptions, but shall indicate the branch of service and the service identification number of the official issuing the prescription, instead of the registration number asked for on the prescription sheets.
  5. If any official or employee exempted by the Division of Drugs and Pharmacies also participates as an individual in any activity for which a registration certificate is required, the medical official concerned must obtain a certificate for such private activity.

## **ARTICLE 6. - REQUIREMENTS FOR THE CLASS B CERTIFICATE**

The following are required for the registration certificate:

1. The requirements listed in Article 8, Categories II, III and IV and Article 37 of Law 50-88;
2. An applicant for a registration certificate to manufacture a controlled substance must not disclose technical details which he regards as a commercial secret, including temperature, pressure, volume and the catalytic used in the process, but must identify every substance which is used or derived from the successive stages of manufacture, for the purpose of notifying it to the Division of Drugs and Pharmacies and the National Drug Control Directorate on drug precursors and secondary products;
3. A person who is registered to dispense for the purpose of research with controlled substances, in accordance with Article 24 of Law 50-88, must submit:
  1. A research report, to include:
    1. The duration in time of the research;
    2. The controlled substance or the precursors used;

3. Evidence of the professional competence of the researchers.
2. The research findings shall, at the request of the interested party, be kept as confidential information, subject to the provisions of Article 30 of Law 50-88.
3. When the research has been completed, all unused controlled substances shall be returned to the Director of the Division of Drugs and Pharmacies.
4. Every application for registration for manufacturing a controlled narcotic substance which involves a process of chemical synthesis (whether derived or not from narcotic materials) shall be accompanied by a summary of the process of synthesis. This summary must:
  1. Identify the substances with which the substance will be prepared;
  2. Identify the substances to be formed as the result of each successive stage of the process;
  3. Indicate, in each case, whether the substance will be isolated and weighed or measured, or whether it will remain in solution in a process of continuous production.

## **ARTICLE 7. - REGISTRATION OF SEPARATE PREMISES**

A registration certificate is required for each premises or main business establishment where controlled substances are manufactured, distributed or dispensed.

1. The following premises or establishments will not be regarded as places where controlled substances are manufactured, distributed or dispensed:
  1. Any store where controlled substances are kept at the request of a registered person, unless such substances are distributed directly from the store to other registered persons, or to persons not under an obligation to register.
  2. The office used by agents of a registered person where the distribution of controlled substances is requested, carried out or supervised, but in which such substances are not stored except for display purposes or as samples for distribution to professionals, and which is not used as a distribution or dispatch point for sales.
  3. The office used by a professional in which controlled substances are dispensed, but where they are neither administered nor handed out as a standard part of professional practice, and where no controlled substances are kept except the samples ordinarily received by the professional.

The professional must keep a written record of the controlled substances received as samples, and of how these are ultimately disposed of;

2. The use of homes or residences for storing controlled substances is expressly forbidden;
3. The following are exempt from the foregoing provision:
  1. Individual professionals;
  2. The end consumer;
  3. Visiting doctors, who may keep samples for distribution for a period not exceeding 30 days, storing them in a metal cabinet under lock and key.

## **ARTICLE 8. - APPLICATION FORMS**

Every person wishing to obtain a certificate must apply for and fill in the forms for Classes B/A, which can be obtained from the Division of Drugs and Pharmacies and/or the National Drug Control Directorate.

1. Every registered person will be sent the registration forms by post, approximately 60 days

- before the expiry of his registration. A person not receiving these forms 45 days before the date of expiry of his registration should immediately notify the Division of Drugs and Pharmacies and/or the National Drug Control Directorate.
2. Every application for registration must include all the information requested on the forms, unless a particular question does not apply, including the licence number and the name of the establishment requesting renewal.
  3. Every attachment to the application and any other document submitted as part of the application must be signed by the applicant, if an individual, or by the President or Secretary in the case of a company. A person who has previously been registered may authorize one or more individuals to sign registration applications for him, completing the form Class B and 20-65 for return to the Division of Drugs and Pharmacies. This form will be supplied by the Division of Drugs and Pharmacies, and will be signed by the person authorized to sign applications, and will include the signature of the person who is authorized to sign applications, as acceptance of delegated authority. Intention to revoke will be notified in writing and will not be effective until approval has been obtained from the Division of Drugs and Pharmacies.
  4. Government institutions are exempt from the payment of duties for registration.

## **ARTICLE 9. - DATE AND FORM OF PAYMENT OF DUTY, REIMBURSEMENT**

Registration duties shall be payable when the application is made. Payment will be made against a receipt from the National Drug Control Directorate for the amount of the duty.

## **ARTICLE 10. - ADDITIONAL DUTY**

The Director of the Division of Drugs and Pharmacies and of the National Drug Control Directorate may require any applicant to submit such documents or written declarations as he considers necessary in order to decide whether to accept the application and whether to grant or refuse registration. If the applicant does not submit the documents or written declarations within the period of time allowed, the National Drug Control Directorate shall conclude that the opportunity to present the documentation is forfeited..

## **ARTICLE 11. - AMENDMENTS TO APPLICATIONS, WITHDRAWAL**

An application for registration may be amended or withdrawn, and may be cancelled if the applicant so requests, or if official correspondence relating to the application is not answered; where such correspondence is sent by certified or registered post with notice of receipt, to the address shown on the application, the applicant will be deemed to have withdrawn the application.

## **ARTICLE 12. - DISPATCH OF THE REGISTRATION CERTIFICATE**

The Division of Drugs and Pharmacies shall send a Class A or Class B certificate to the applicant if so warranted. If not, the application will be refused, following the procedure laid down in this Regulation.

1. To determine whether the registration certificate should be issued, the Director of the Division of Drugs and Pharmacies may:
  1. Review the application;
  2. Check any other additional information relating to the application;
  3. Inspect the establishment or premises of the applicant.
2. The Class A and Class B certificate shall contain:

1. The name;
  2. The address of the holder;
  3. The registration number;
  4. The categories of controlled substances which the holder is authorized to handle;
  5. The category of the certificate, with the amount of duty paid or the exemption from duty;
  6. The date on which registration will expire.
3. The holder shall display the registration certificate in a prominent place in the registered premises, which shall be readily accessible to the Controller.
  4. Each registration certificate shall be sent solely in the name of the owner and/or the company, and not in the name of the premises or establishment, except in the case of State institutions, in which case it will be sent in the name of the institution.
  5. The certificate must be sent for one financial year.

### **ARTICLE 13. - EXTENSION OF REGISTRATION**

If a person carrying on business under a registration previously granted which has been neither revoked or suspended has applied for a fresh certificate at least forty five days before the expiry date of the existing certificate, the National Drug Control Directorate shall grant the new certificate for the date on which the existing one expires.

1. The Director of the National Drug Control Directorate may extend any registration under the circumstances described in this article (even if the registered person has not requested registration at least 45 days before expiry of the current registration) on his own initiative or at the request of the applicant, when he decides that the extension will not be prejudicial to public health and safety and that the applicant fulfils the requirements of the Law and of this Regulation.

### **ARTICLE 14. - EXPIRATION OF REGISTRATION**

A registration shall expire when the person for whom it was issued dies, ceases to have legal existence, discontinues business or professional practice or changes his name from the name appearing in the registration certificate. Any change in the foregoing particulars must be notified to the Division of Drugs and Pharmacies and to the National Drug Control Directorate within thirty (30) days.

1. In the event of a change of name, the person shall request a new registration certificate before the date when the change becomes effective, submitting an application and paying appropriate duty as if for a fresh application.
2. A change of address of the premises or establishment of a non-professional individual shall not cause the registration to lapse, but the new premises may not be occupied without the prior consent of the Division of Drugs and Pharmacies.
3. A change of address of a professional, whether an individual or an institution, shall not cause the registration to lapse, and only requires notification of the change to the Division of Drugs and Pharmacies, for the purpose of amending the address on the registration certificate, the prescription forms or any other official document or form.

### **ARTICLE 15. - TRANSFER OF REGISTRATION**

No registration or authorization shall be transferred, once granted.

### **ARTICLE 16. - REFUSAL, CANCELLATION OR SUSPENSION OF**

## **REGISTRATION**

The Director may refuse, suspend or cancel any registration for any of the reasons listed in the Law or in this Regulation.

Such refusal, suspension or renewal shall be for an appropriate period.

### **ARTICLE 17. - REASONS FOR REFUSAL, SUSPENSION OR CANCELLATION OF A REGISTRATION**

The Ministry of Public Health and Social Welfare, in cooperation with the National Drug Control Directorate, may refuse, suspend or cancel an application for registration for any of the following reasons:

1. For the reasons listed in Article 43;
2. Because the establishment does not have the necessary facilities or meet the legal requirements specified by the Ministry of Public Health and Social Welfare;
3. When it is found that grant of registration would be contrary to the public interest, because it would adversely affect or endanger the health, safety or welfare of the community.

### **ARTICLE 18. - PROCEDURE FOR REFUSAL, SUSPENSION OR CANCELLATION OF REGISTRATION**

Before refusing, suspending or cancelling a registration, the Ministry of Health and Social Welfare shall notify to the interested party, by certified mail to the address shown on the registration or application, with an order to show cause why the registration should not be refused, cancelled or suspended.

1. In the order to show cause, the applicant or certificate holder shall be informed that he must appear before the Director of the Division of Drugs and Pharmacies, at the place and date indicated, which shall not be less than 30 days following the notification, to show cause why his registration should not be refused, suspended or cancelled. The certificate holder or applicant may, if he so wishes, submit his reasons in writing to the Secretary of the Ministry of Public Health and Social Welfare on or before the date stated in the order.
2. If the interested party fails to comply with the foregoing, or if the Secretary of State for Public Health and Social Welfare so decides, after examining the reasons given by the certificate holder or applicant, he shall issue an order refusing, suspending or cancelling the registration. In this order the applicant will be informed of his right to request a public hearing on the refusal, suspension or cancellation of registration, in accordance with the provisions contained for this purpose in this Regulation.
3. On receiving an order suspending or cancelling a registration, the certificate holder shall immediately hand over to the Division of Drugs and Pharmacies:
  1. His Class A and Class B Certificate.
  2. The official request forms which he possesses.
  3. All the controlled substances in his ownership or control in accordance with his registration, to be placed under seal in the custody of the Director of Drugs and Pharmacies.

### **ARTICLE 19. - IMMEDIATE SUSPENSION**

The Ministry of Public Health and Social Welfare may suspend any registration at the moment of, or at any time following, notification to the certificate holder of an order to show cause, in any case in which imminent risk to public health or safety is found to exist. If the Secretary orders such suspension, he shall give notice, with the order to show cause according to the foregoing section, of an order of immediate suspension, stating the facts which would endanger public health or safety.

1. When given notice of the order of immediate suspension, the certificate holder shall immediately comply with paragraph C of the foregoing section.
2. Every certificate holder whose registration is suspended under this article may request a public hearing concerning the cancellation or suspension of his registration, for a date prior to that stated in the order to show cause. On examining the request, the Ministry of Public Health and Social Welfare shall fix a date within the shortest possible time.

## **ARTICLE 20. - EFFECTIVE PERIOD OF SUSPENSION OR CANCELLATION**

Every suspension shall continue to have effect pending completion of all the procedures relating to the cancellation or suspension, including judicial review, unless previously rendered ineffective by the Ministry of Public Health and Social Welfare, or by a competent court.

## **ARTICLE 21.- PRESCRIPTION FORMS**

Every professional (doctor, dentist, veterinary surgeon) must provide himself with a book of forms 2064 as defined in Article 31 of Law 50-88.

These forms may only be used for the purpose of issuing prescriptions.

## **ARTICLE 22. - FORMAT OF THE FORMS**

The prescription forms shall be issued in blocks of 100 originals.

These forms must be previously numbered in sequence for each professional, and must bear his name, address and registration number; in the case of an individual professional, his specialism must also be included. These details may not be altered without the prior consent of the National Drug Control Directorate.

## **ARTICLE 23. - METHOD OF OBTAINING FORMS**

The forms will be supplied by the Inland Revenue on request and in accordance with the requirements of this Regulation.

## **ARTICLE 24. - PAYMENT FOR FORMS**

An individual professional who requests blocks of forms shall pay for the cost of printing the forms. This payment will be made against a receipt from the Inland Revenue.

## **ARTICLE 25. - APPLYING FOR FORMS**

The application for prescription forms must be made in writing to the National Drug Control Directorate, and must be signed by the individual professional, or in the case of an institution, by its authorized representative.

1. Each application should be accompanied by:
  1. The Inland Revenue receipt for the total cost of printing the forms.
  2. A written explanation of the professional's need for the quantity of books of prescription forms requested. This explanation will be given in the light of the average number of prescriptions issued by the professional on a daily basis. The statement will be subject to verification by the National Drug Control Directorate, which may refuse to supply the quantity of books of prescription forms requested if the quantity is not warranted.

## **ARTICLE 26. - METHOD OF ISSUING THE PRESCRIPTION**

A professional who issues a prescription will give the original of the form to the patient and retain the copy. The copy of the prescription form will be kept by a duly registered professional for a period of one year from the date of issue, in numerical order, and must remain available for inspection by any official duly authorized by the Director of the National Drug Control Directorate. In the case of a prescription form from a professional institution, its name must be included in legible form in addition to the signature.

## **ARTICLE 27.- DISTRIBUTION OF FORM 2064**

The books 2064 of official prescription forms will be bound in blocks with carbon paper, and distributed as follows:

1. Original to the pharmacy;
2. First copy to the interested party;
3. Second copy to the professional;
4. Third copy to the National Drug Control Directorate;
5. Fourth copy to the Ministry of Public Health.

The 2064 forms will be for the exclusive use of the professional, and may not be transferred or assigned under any pretext.

## **ARTICLE 28. - CANCELLATION OF OR DAMAGE TO THE FORM**

If any form is cancelled or damaged, the professional concerned must write the word "void" on it and retain the original and the copies, also to be cancelled, as this Regulation requires.

## **ARTICLE 29. - THEFT OR LOSS OF FORMS**

Any theft or loss of the prescription forms must be notified by the professional concerned by the speediest possible method to the National Drug Control Directorate, within three days of becoming aware of the theft or loss.

## **ARTICLE 30. - EFFECTIVENESS OF THE PRESCRIPTION FORMS**

From the date on which this Regulation comes into force, individual professionals have 60 days to acquire and begin using the prescription forms. Professional institutions have 180 days for the same purpose.

## **CHAPTER III GENERAL PROVISIONS ON PSYCHOTROPIC PRODUCTS**

### **Article 1.**

The import, export, transit, production, manufacture, fractionation, preparation, distribution, transport, transfer under any pretext, storage, possession, holding and use of drugs, preparations and other psychotropic products will be governed by the rules of this Regulation.

### **Article 2.**

References in the laws, regulations, decrees, resolutions and other provisions in force to "substances or pharmaceutical products causing dependence" will be understood to designate the psychotropic products covered by this Regulation.

### **Article 3.**

Control of the import, export, transit, production, manufacture, fractionation and distribution of psychotropic products shall be the responsibility of the Division of Drugs and Pharmacies.

The health services shall be responsible for controlling activities of preparation, transport, transfer under any pretext, storage, possession, holding and use of psychotropic products, within their field of competence.

### **Article 4.**

The import, export, transit, extraction, production, manufacture, fractionation, preparation, distribution, transport, transfer under any pretext, storage, possession and holding of the drugs, preparations and pharmaceutical products included in List I are prohibited on the national territory.

### **Article 5.**

The provisions of this Regulation are without prejudice to the application to psychotropic drugs, preparations and pharmaceutical products of Law 50-88 and other supplementary rules of the Health Code, in so far as they are relevant and compatible with this Regulation.

### **Article 6.**

Psychotropic drugs, preparations and products may only be imported to or exported from the national territory by laboratories making pharmaceuticals, distributors and medical or scientific research institutions, with prior authorization of the Ministry of Public Health and the National Drug Control Directorate.



For this purpose, the establishments or entities concerned shall communicate to the Ministry of Public Health, in January of each year, their anticipated needs for imports or exports of these products during the subsequent calendar year, so that the Ministry, on the basis of the information supplied by the applicant, can determine the quantity it may import or export during this period.

### **Article 7.**

In order to import or export psychotropic products included in the approved estimates, each establishment must act within thirty days of the date of the application.

Authorization will be granted by means of an official import or export certificate, which must be issued within thirty days of the date of the application.

### **Article 8.**

The import application must state the following details:

1. Name and registered address of the establishment or its legal representative, in the case of a legal person;
2. Name of the head of the establishment or the professional of the area of health responsible, in the case of medical or scientific research bodies;
3. Name and registered address of the exporter and country of origin of the product;
4. Generic name and chemical description identifying the drug or product;
5. Desired quantity to be imported;
6. Pharmaceutical form, name and kind of container, in the case of pharmaceutical preparations or products;
7. Customs point through which the product is to enter.

### **Article 9.**

The export application must state the following details:

1. Name and registered address of the exporting establishment and of its representative, in the case of a legal person;
2. Name and registered address of the recipient and country of destination;
3. Head of the establishment;
4. Generic name and identifying chemical description of the drug or product;
5. Desired quantity of the product to be exported;
6. Pharmaceutical form, name and kind of container, in the case of pharmaceutical preparations and products;
7. Number and date of the import certificate and authority which issued it in the country of destination;
8. Customs point through which the export will take place.

### **Article 10.**

Official import and export certificates will be valid for ninety (90) days from the date of issue.

### **Article 11.**

Where psychotropic products import of which has been authorized are to pass through any customs point, the customs service will require a certificate issued by the Ministry of Health, stating the authorized place at which the substances are to be deposited, and the route and the means of transport to be used to convey them from the customs area to the specified place.

The Ministry of Health must give its opinion concerning the certificate referred to in the foregoing paragraph, no later than three working days from the date of the request and, if the request is rejected, must give reasons for its decision.

If for any reason the interested party does not receive the psychotropic products in the quantities indicated in the certificate, he must immediately notify the Ministry of Health, with a view to investigating the reasons why the substances have been mislaid, lost or partially removed.

## **Article 12.**

Psychotropic substances which enter the country in transit may not be subjected to any treatment or handling which may alter their nature or packaging, except in defined instances authorized by the Ministry of Health and the National Drug Control Directorate.

## **PRODUCTION AND SALE**

### **Article 13.**

The production, manufacture, fractionation or preparation of psychotropic products may only take place in chemical laboratories making pharmaceuticals, pharmacies and other authorized establishments.

For this purpose, the owner of the establishment will request authorization from the Ministry of Health in January each year, indicating the quantity of psychotropic products which it is intended to extract, produce, manufacture, fractionate or prepare during the subsequent calendar year. The Ministry may object to the request within the thirty days following its submission, after which it is deemed to have been approved.

### **Article 14.**

Every establishment which is authorized to extract, produce, manufacture, fractionate or prepare psychotropic products must keep an up to date register, which shall remain permanently at the disposal of the health authorities and of the National Drug Control Directorate, and must contain the following information:

1. The quantities and origins of the drugs or psychotropic substances which have entered the establishment, and the dates of entry;
2. The quantities of psychotropic substances manufactured by the establishment, the dates of manufacture and the names and registered addresses of the recipients;
3. The corresponding balances.

These establishments must communicate the following information to the Ministry of Health, before 15 January each year:

1. The total quantity of psychotropic drugs which have entered the establishment during the

- previous year, and the balances existing on the date of the communication;
2. The total quantities of psychotropic products extracted or prepared during the same period, and the balances existing on the date of the communication;

## **Article 15.**

The establishments referred to must keep up to date a record book of psychotropic substances, approved by the Ministry of Health and inspected by the National Drug Control Directorate, to which this task is assigned, and in which the following data are registered in full in respect of each drug or psychotropic product, indicating its commercial name where appropriate:

1. Incoming items:
  1. Date;
  2. Quantity;
  3. Number and date of the resolution which authorized the entry, distribution or transfer as applicable;
  4. Supplier, number and date of the invoice, guide and other appropriate document;
  5. Series number where relevant.
2. Outgoing items:
  1. Date;
  2. Quantity;
  3. Name of the drug, medicine containing it or psychotropic product and series number where appropriate;
  4. Number and date of the invoice, guide and other internal control document of the establishment;
  5. Number of the prescription form, registration number of the prescription in the case of a preparation;
  6. Name of the surgeon or professional issuing the prescription, as appropriate, and identity document;
  7. Name and registered address of the addressee or patient;
  8. Name and identity document of the recipient.
3. Balances

## **Article 16.**

Containers for psychotropic products may not hold any quantity of less than ten or more than thirty posological units. The contents of clinical containers intended exclusively for use in welfare establishments may be higher than this.

The labels on the containers must state the conditions of sale of the product, and bear the legend, in black letters on a white background: "Subject to psychotropic control". The labels must also display a five-pointed star in blue, of a size not less than one sixth of their surface area.

## **Article 17.**

The start, suspension or completion of the preparation and/or marketing of any psychotropic product must be communicated by the establishment concerned to the Ministry of Health and the National Drug Control Directorate, within the thirty subsequent days. Failure to comply with this requirement may involve withdrawal of the authorization and health registration of the product.

Before resuming manufacture or sale of a psychotropic product the preparation of which has

been suspended, the establishment must notify the Ministry of Health.

### **Article 18.**

Only the establishments indicated in Article 8 may acquire natural substances and narcotic drugs, by prior permission of the Ministry of Health, granted on written request from the head of the establishment. Both the vendor and the recipient must retain copies of the permits in question.

## **CHAPTER IV GENERAL PROVISIONS ON NARCOTIC PRODUCTS**

### **Article 1.**

The Ministry of Health and Social Welfare, together with the National Drug Directorate, shall be responsible for monitoring the import, export, transit, production, manufacture, fractionation and distribution of narcotic products.

The health services, for their part, shall be responsible for monitoring activities concerned with the preparation, transport, transfer under any pretext, storage, possession, holding and use of narcotic products, within their areas of jurisdiction.

### **Article 2.**

The import, export, transit, production, manufacture,, preparation, distribution, transport, transfer under any pretext, sale, possession and holding of acetorphine, cannabis and cannabis resin, ketobemidone, desomorphine, etorphine, heroin and the salts of these substances, as applicable, are prohibited within the national territory. However, in certain cases and for scientific research purposes, use of these substances may be authorized by the Ministry of Public Health and Social Welfare, in the circumstances defined in the relevant decision.

## **IMPORT AND EXPORT**

### **Article 3.**

Narcotic drugs, preparations and products may only be imported to or exported from the national territory by pharmaceutical laboratories, drug stores, pharmacies, hospitals and medical or scientific research institutions, by prior permission of the Ministry of Public Health and Social Welfare (SESPAS).

For this purpose, the establishments or bodies concerned shall notify the Ministry, in January each year, of their anticipated imports or exports of these products for the subsequent calendar year, so that, on the basis of the information provided by the applicant, the Ministry can determine the quantity which may be imported or exported during that period.

### **Article 4.**

In order to import or export substances included in the approved estimates, each establishment must request from the Ministry of Public Health-and Social Welfare (SESPAS), authorization for

each specific product and consignment.

The authorization will be granted by means of an official import or export certificate, which must be issued within thirty days of the date of the application.

An import application must contain the following particulars:

1. The name and registered address of the establishment or its legal representative, in the case of a legal person;
2. The particulars of the technical director of the establishment or the professional for the responsible health area, and where applicable of the medical or scientific research institutions;
3. The name and registered address of the exporter and the country of origin of the product;
4. The generic name and identifying chemical description of the drug or product;
5. The desired quantity to be imported;
6. The pharmaceutical form, the name and nature of the container, in the case of pharmaceutical products or preparations; and
7. The customs point through which the product will be brought into the country.

## **Article 5.**

An export application must contain the following particulars:

1. The name and registered address of the exporting establishment and of its representative, in the case of a legal person;
2. The name and registered address of the intended recipient, and the country of destination;
3. The technical director of the establishment;
4. The generic name and identifying chemical description of the drug or product;
5. The desired quantity of the product to be exported;
6. The pharmaceutical form, the name and nature of the container, in the case of pharmaceutical products or preparations;
7. The number and date of the import certificate and the authority which issued it in the country of destination; and
8. The customs point through which export will be effected.

## **Article 6.**

Official import and export certificates will be valid for four months from the date of issue, and the import or export, as appropriate, must be in all cases take place within a maximum of 6 months from the same date.

## **Article 7.**

Where narcotic products the import of which has been authorized are to transit any customs destination, the Customs Service will require a certificate issued by the Ministry of Public Health and Social Welfare (SESPAS), showing the authorized location at which the substances are to be deposited, and the route and the means of transport to be used to transfer them from the customs premises to the stated place of deposit.

The appropriate Health Service must examine and approve the Certificate referred to in the foregoing paragraph, within three working days of the date of the application, and if rejecting it,

must give reasons for its decision.

### **Article 8.**

When the documentation for the customs destination has been completed and the narcotic products have been withdrawn from the initial storage at customs, they must be placed in the care of the consignee, who may not produce, manufacture, fractionate or distribute them without obtaining the permission of the competent health authority.

This authority must make a decision granting or rejecting permission, or fixing a safety period for making the appropriate health checks, during which the products may not be sold. This decision must be made within three working days of the date on which the interested party informs it that the substances have been taken into the place of deposit, sending a copy of the certificate issued by the Health Service permitting their transfer to the place in question.

If for any reason the interested party does not receive the narcotic substances in the quantities indicated in the Certificate, he must immediately inform the Ministry of Public Health and Social Welfare (SESPAS), for the purpose of investigating the reasons for the misplacement, loss or partial removal of the substances.

### **Article 9.**

Narcotic products entering the country in transit may not be subjected to any operation or treatment which may alter their nature or change their packaging, except in certain cases authorized by the Ministry of Public Health and Social Welfare (SESPAS).

## **PRODUCTION AND STORAGE**

### **Article 10.**

The extraction, production, manufacture, fractionation or preparation of narcotics may only be carried out in pharmaceutical laboratories, pharmacies and other authorized establishments.

For this purpose, the proprietor of the establishment shall request permission from the Ministry of Public Health and Social Welfare (SESPAS) before 1 September each year, stating the quantity of narcotics which it is intended to extract, produce, manufacture, or prepare during the subsequent calendar year. The Ministry may object to the request within thirty days of its submission, following which it will be deemed to be approved.

### **Article 11.**

Every establishment which extracts, produces, manufactures, or prepares narcotic substances must keep a special record, which shall be permanently held at the disposal of the health authority, and which must contain the following particulars:

1. The quantities and sources of the narcotic drugs or products which have entered the establishment, and the dates of entry;
2. The quantities of narcotic products manufactured by the establishment, the dates of manufacture and the names and registered addresses of the intended recipients; and

3. The quantities remaining.

These establishments must communicate the following information to the Ministry of Public Health and Social Welfare, before 15 January each year:

1. The total quantity of narcotic drugs which entered the establishment during the previous year, and the balances held on the date of the communication; and
2. The total quantities of narcotic products extracted or elaborated during the same period, and the balances held on the date of the communication.

## **Article 12.**

These establishments must keep up to date a Control Book of Narcotics, approved by the Ministry of Public Health and Social Welfare (SESPAS), or by the health service entrusted with this function, in which the following details will be recorded separately for each narcotic drug or product, stating their commercial names where appropriate:

1. Incoming items:
  1. Date;
  2. Quantity;
  3. Number and date of the decision which authorized the entry, distribution or transfer as relevant;
  4. The supplier, the number and date of the invoice, guide or other document, as appropriate; and
  5. Series number, where appropriate.
2. Outgoing items:
  1. - Date;
  2. - Quantity;
  3. - Name of the drug, medicament containing it or narcotic product, and series number, where appropriate;
  4. - Number and date of the invoice, guide and other internal control document of the establishment;
  5. - Number of the prescription, registration number of the prescription in the case of a magisterial preparation;
  6. - Number of the doctor or professional who issued the prescription, and identity card;
  7. - Number and registered address of the intended recipient or patient;
  8. - Number and identity card of the recipient; and
3. Balances held.

## **Article 13.**

The containers for narcotic products may not contain more than 12 posological units. The contents of clinical containers intended exclusively for used in welfare establishments may exceed this amount.

The labels on the containers must state the condition of sale of the product, and the legend in black letters on a white background: Subject to Narcotics Control. The labels will also display a five-pointed star in red, the size of which should not be less than one sixth of the surface area.

## **Article 14.**

Preparations or products containing narcotics from lists II and III may only be dispensed to the public in pharmacies and laboratories by means of form 2064.

Without prejudice to the foregoing, in the case of pharmaceutical preparations and products containing minimum dosages of narcotic drugs mixed with one or more other ingredients, the health authority may arrange for another means of sale.

## CHAPTER V Precursors

### Paragraph 1.

The following precursors, solvents and chemical reactants are regarded as controlled substances, and therefore subject to all the legal provisions of this Law.

[(1)] N.C.C.A.	[(2)] S.A.	NAMES	SYNONYMS
29.02	29.03	Bencil chloride	[ <i>cloro metil benceno</i> ; <i>alfa clorotolueno</i> ]
29.13	29.14	[3,4 <i>metil enodioxifenil 2 propanona</i> ]	[3,4 <i>metilenodioxifenilacetona</i> ; 3,4 <i>metilenodioxifenil-metil-cetona-piperonil-metilacetona</i> ]
29.27	29.26	Benzene cyanide	Benzene acetonitrile; 2-phenyl acetonitrile, [ <i>alfa toluinitrilo</i> , <i>cianotolueno</i> ]
29.27	29.26	[ <i>bromo</i> ] cyanide, bencil	[ <i>Bromobenceno acetato de nitrilo</i> ]
29.35	29.39	Piperidine	[ <i>Hexahidro piridina</i> ; <i>penta metilenamina</i> ]
		Piperonal	Heliotropina; [3,4 <i>metilendroxi</i> ; benzaldehyde, [ <i>piperonilico</i> ] aldehyde
29.42	29.39	Ephedrine, its isomer salts	[ <i>alfa [1-(metilamino) etil] benceno mitanol</i> ; <i>alcohol alfa [1-(metilamino) propilbencilico</i> ; <i>2-metil amino-1-fenil-1-hidroxi-2-metil amino propano</i> ; <i>alfa hidroxi-beta-metil amino propil benceno</i> ]
29.42	29.39	[ <i>Seudo efedrina</i> ] its salts, optical isomers and salts of its optical isomers[(3)] D.C.I.	[2- <i>metil amino-1-fenil-1-propanol</i> : <i>1-fenil-1-hidroxi-2-metil aminopropane</i> ]; -d-isoephedrine

### "OTHER CHEMICAL PRODUCTS"

[(1)] N.C.C.A.	[(2)] S.A.	NAMES	SYNONYMS
22.08	22.07	Ethyl alcohol	Ethanol alcohol, anhydrous hydroxide [ <i>de etilo</i> ] alcohol
22.09	22.08	[*] Isopropyl alcohol	[2- <i>propanol</i> ; <i>esopropanol</i> ; <i>alcohol propilico secundario</i> ]
		[* ] Methyl alcohol	Methanol, [ <i>carbinol</i> ] wood alcohol
28.06	28.06	Hydrochloric acid	[ <i>acido muriatico</i> ], hydrogen chloride in watery solution
28.08	28.07	Sulphuric acid	Vitriol oil, hydrogen sulphate, fuming disulphuric acid of carbon



28.15	28.13	Carbon sulphur	Carbon disulphur
28.116	28.14	Anhydrous ammonia [ o endi solucion acuosa]	[ <i>aguan amoniaca</i> ] ammonium hydroxide, [ <i>hidrato amonico</i> ] ammoniac in watery solution
28.17	28.15	Potassium hydroxide [*] Calcium hydrate	Caustic potash Calcium hydrate, calcium hydroxide, lime hydrate, slaked lime
28.28	28.33	Sodium sulphate	[ <i>sulfato disodico, sulfato sodico, anhidro, sulfato sodico desecado, torta de sal thenardita (mineral). En la forma hidratada sulfato de sodico dicahidratado, sal glauber merabiliter (mineral)</i> ]
28.42	28.36	Potassium carbonate	Neutral potassium carbonate, pearl ash, tartar salt
28.42	28.36	Soda carbonate	Neutral soda carbonate, [ <i>soda solvay, ceniza sosagoza calcinada</i> ]
28.47	28.41	Potassium permanganate	Potassium permanganate, [ <i>sal de potasio del acido permanganico, camaleon mineral</i> ]
29.02	20.03	Methylene chloride	[ <i>diclometano</i> ] methylene bichloride
29.02	29.03	Tricloroetileno [*] Hydrogen peroxide [*] Queroseno [*] UreaOxalic acid	[ <i>tricloroeteno</i> ]Oxygenated water, hydrogen bioxide, hydrogen dioxide Kerosene, kerosina, lamp oil [ <i>carbomida</i> ][ <i>acido etanoico</i> ]

## CHAPTER VI PROVISIONS RELATING TO OFFENCES AND LAUNDERING OF ASSETS CONNECTED WITH ILLICIT TRAFFIC IN DRUGS AND CONTROLLED SUBSTANCES IN THE DOMINICAN REPUBLIC

### ARTICLE 1 JURISDICTION

1. The offences defined in Law 50-88 on Drugs and Controlled Substances in the Dominican Republic, of 30 May 1988, and its amendments, will be investigated by the competent authority and will be prosecuted and tried by the court, regardless of whether the offence of illicit traffic or related offences occurred in another foreign jurisdiction, without prejudice to extradition where this is carried out according to law.

### ARTICLE 2 PROTECTIVE MEASURES AGAINST GOODS, PRODUCTS OR INSTRUMENTS

1. In accordance with procedural rules and Law 50-88 and its amendments, the court shall at any time, without notification or prior hearing, make an order for seizure or other protective measure for the purpose of keeping available goods, products or instruments relating to an offence of illicit traffic or related offences, until a final judgment is handed down.

### ARTICLE 3 CONFISCATION OF GOODS, PRODUCTS OR INSTRUMENTS

1. When a person is found guilty of an offence of illicit traffic or related offences, the court will order that the goods, products or instruments connected with the offence are

- confiscated, and will dispose of them in accordance with the law.
2. Where any of the goods, products or instruments referred to in the foregoing paragraph cannot be confiscated as the result of any act or omission by the convicted person, the court will order the seizure of any other goods of the convicted person to an equivalent value, and will order him to pay a fine of that amount.

#### **ARTICLE 4 THIRD PARTIES IN GOOD FAITH**

1. The measures and sanctions to which Article 2 and 3 of this Regulation refer will apply without prejudice to the rights of third parties acting in good faith.
2. In accordance with procedural rules, proper notification will be given so that all those able to show a legitimate legal interest to the goods, products or instruments received as a result of the commission of the offence of illicit traffic and related offences are able to assert their rights.
3. Lack of good faith on the part of a third party may be inferred at the discretion of the court or as a result of the investigation procedure of the National Drug Control Directorate, and from the objective circumstances of the case.
4. In accordance with procedural rules and Law 50-88 and its amendments, the court or the National Drug Control Directorate, pursuant to the investigation procedure, will arrange for the confiscated goods, products and instruments to be handed over to the claimant when it has been shown and demonstrated that:
  1. The claimant has a legitimate legal interest in the goods, products or instruments;
  2. No form of participation in an offence of illicit traffic or related offences which are the subject of proceedings can be imputed to the claimant;
  3. The claimant was unintentionally ignorant of the illegal use of the goods, products or instruments, or if aware of it, did not voluntarily consent to such use;
  4. The claimant did not acquire any right to the goods, products or instruments of the indicted person in circumstances from which it might reasonably be concluded that such right was transferred to him for the purpose of evading subsequent confiscation; and
  5. The claimant did everything possible to prevent the illegal use of the goods, products or instruments.

#### **ARTICLE 5 DESTINATION OF THE CONFISCATED GOODS, PRODUCTS OR INSTRUMENTS**

1. Whenever goods, products or instruments confiscated pursuant to Article 3 are not to be destroyed and are not harmful to the public, the court will proceed as provided in Articles 35 and 108 of Law 50-88 and its amendments.

#### **ARTICLE 6 DESTINATION OF THE CONFISCATED GOODS, PRODUCTS OR INSTRUMENTS**

1. Whenever goods, products or instruments confiscated pursuant to Article are not to be destroyed and are not harmful to the public, the court will proceed as provided in Articles 35 and 108 of Law 50-88 and its amendments.

#### **ARTICLE 6 GOODS, PRODUCTS OR INSTRUMENTS FROM OFFENCES COMMITTED ABROAD**

1. In accordance with the law, the court may order the seizure or confiscation of goods,

products or instruments located in its territorial jurisdiction which are connected with an offence of illicit traffic or a related offence committed against the laws of another country, when such an offence, if committed within its jurisdiction, would also be regarded as such.

## **ARTICLE 7 FINANCIAL INSTITUTIONS AND ACTIVITIES**

1.
  1. Commercial banks, development banks, construction mortgage banks, the National Housing Bank, savings and loans associations, commercial lending institutions, small loan funds, credit card issuing firms, financial groups, savings and credit cooperatives and any other entity which by the nature of its financial operations acts as such according to the legislation in force, whether under public, private or mixed ownership;
  2. Natural or legal persons engaged in brokerage or dealing in shares or securities;
  3. Natural or legal persons dealing in currency exchange.
2. Natural or legal persons whose activities include the following shall also be regarded as equivalent to financial institutions:
  1. Regular operations in the exchange of cheques and other types of negotiable securities;
  2. Regular issuing, sales or redemption operations for travellers cheques or postal giro cheques;
  3. Regular transfers of funds, either through the financial bodies, by special mail, by electronic means or by any other means;
  4. Any other activity subject to supervision by the monetary authorities.

## **ARTICLE 8 IDENTIFICATION OF CLIENTS AND RECORD-KEEPING**

1. The financial institutions must keep named accounts; they may not keep anonymous accounts or accounts under fictitious or false names.
2. The financial institutions must register, and verify by authentic means, the identity, standing, registered address, legal capacity, occupation and corporate aims of the persons concerned, as well as other identification particulars, whether they are occasional or regular clients, by means of identity documents such as a passport, an identity card or electoral registration card, birth certificates, driving licence, or any other official documents, whenever commercial relations are established, especially the opening of new accounts, the issue of deposit books, and the carrying out of cash transactions exceeding the national currency equivalent of US\$10,000.
3. The financial institutions must take steps to obtain and conserve information concerning the true identity of the persons (natural or legal) on whose behalf an account is opened or a transaction performed, especially where there is any doubt as to whether such clients are in fact operating on their own behalf.
4. Financial institutions must retain for at least five (5) years from the transaction records of the information and documentation required in this article, whether by means of the documents themselves, microfilms, or any other electronic means of conserving documentation and information.
5. Every financial institution will be bound, at the request of the court and/or the National Drug Directorate, via the Banking Superintendent, to provide information about any account which has been opened for a client.

## **ARTICLE 9 AVAILABILITY OF RECORDS**

1. Financial institutions must, within a period of not more than seventy-two (72) working

hours from the date of receipt of the request, supply information requested from them by the competent authorities concerning the information and documentation referred to in the foregoing article, for use in criminal investigations and proceedings as appropriate, in connection with an offence of illicit traffic or related offences, or breaches of the provisions of Law 50-88 and its amendments.

The financial institutions may not disclose to any person the fact that certain information has been requested by or supplied to the court or competent authority. This information may be shared with the competent authorities of another foreign territorial jurisdiction, in accordance with legal procedures and the rules of international law.

2. The competent authorities will treat as confidential the information referred to in this article, except to the extent that such information is needed in criminal investigations and proceedings connected with the offences of illicit traffic and related offences, as specified in Law no. 50-88 and its amendments.
3. Legal provisions referring to banking secrecy shall not constitute an impediment to compliance with this article, provided the information is requested through the Banking Superintendent.

## **ARTICLE 10 RECORD OF TRANSACTIONS**

1. Every financial institution must register, on a form designed by the Banking Superintendent, each transaction in national or foreign currency exceeding the national currency equivalent of US\$10,000.

The financial institutions may submit to the Banking Superintendent a list of clients (natural or legal persons) whose cash transactions, by the nature of their operations, exceed the national currency equivalent of US\$10,000, in order to be exempted from these provisions.

The Banking Superintendent shall, within a suitable period, give approval and reject a client who does not fulfil the specified requirements.

2. The forms referred to in the foregoing paragraph shall, for each transaction, contain at least the following particulars:
  1. The identity, signature and address of the person physically carrying out the transaction;
  2. The identity and address of the person on whose behalf the transaction is carried out;
  3. The identity and address of the beneficiary or recipient of the transaction, if any;
  4. The identity of the accounts affected by the transaction, if any;
  5. The kind of transaction concerned, such as cash deposits, exchange of currency, purchase of cheques and transfers effected by or through the financial institution;
  6. The identity of the financial institution in which the transaction was performed; and
  7. The date, time and amount of the transaction.
3. This record must be made accurately and in full by the financial institution on the day on which the transaction is made, and must be kept for at least five (5) years from that date.
4. Multiple cash transactions which together exceed the national currency equivalent of US\$10,000 will be regarded as a single transaction if carried out by or on behalf of a particular individual in the course of a working day. In that case, where the financial institution, its employees, officials or agents become aware of such transactions, they must register them on the form designed for that purpose.
5. Where transactions are effected on their own account between the financial institutions

defined in Article 7, paragraph 1) A), and are subject to supervision by the national banking or financial institutions, registration in the form stipulated in this article will not be required.

6. These records must be kept available, via the Banking Superintendent, to the court or the National Drug Control Directorate, according to law, for use in criminal investigations and proceedings as appropriate, concerning an offence of illicit traffic or related offences, or breaches of the provisions of Law 50-88 and its amendments.
7. When deemed appropriate, the court or the National Drug Control Directorate may request the financial institutions to present via the Banking Superintendent, within the period specified in Article 9, paragraph 1), of this Regulation, the form provided for in paragraph 2) of this article. This document will serve as evidence or as official information and will be used for the purposes defined in paragraph 6) of this article.
8. The financial institutions defined in Article 7, paragraph 1) a) of this Regulation must make available to the court, to the National Drug Control Directorate and to the international institutions, through the Banking Superintendent and, where appropriate, the bodies defined in paragraphs b) and c) of that article, through the tax authorities, such information as is requested when necessary, provided it is required in order to elucidate criminal proceedings for illicit traffic and related offences.
9. Legal provisions relating to banking secrecy or confidentiality shall not constitute an impediment to compliance with this article, when the information is requested, via the Banking Superintendent, by the court or by the National Drug Directorate.

## **ARTICLE 11 COMMUNICATION OF SUSPECT FINANCIAL TRANSACTIONS**

1. Financial institutions shall pay special attention to all transactions, completed or otherwise, which are complex, unusual, or significant, and to all types of unusual transactions and those which are not significant but are regular and do not have any obvious legal economic basis.
2. If they suspect that the transactions described in paragraph 1) of this article may constitute or be connected with activities relating to illicit traffic and related offences, the financial institutions must immediately notify the authorities of the Banking Superintendent.
3. The financial institutions may not disclose to any person the fact that information has been requested by or supplied to the court, the Banking Superintendent or the National Drug Control Directorate.
4. When the communication referred to in paragraph 2) of this article is made in good faith, the financial institutions, their employees, officials, directors, proprietors and other representatives authorized by law shall be exempt from civil and criminal responsibility, as appropriate, for complying with this article or for disclosing information which is restricted either by contract or by any other legislative, regulatory or administrative provision, whatever the outcome of the communication.

## **ARTICLE 12 RESPONSIBILITIES OF THE FINANCIAL INSTITUTIONS**

1. The financial institutions or their employees, officials, directors, shareholders and other representatives who, acting in that capacity, participate and/or act as accomplices in an offence of illicit traffic or related offences, shall be subject to the sanctions provided in Law 50-88 on Drugs and Controlled Substances and its amendments.

When complicity is shown on the part of the financial institutions, they shall be subject to the measures laid down in Article 104.

## **ARTICLE 13 PROGRAMMES COMPULSORY FOR THE FINANCIAL**

## **INSTITUTIONS**

1. Financial institutions under the regulation and supervision referred to in Article 15 of this Regulation must adopt, develop and execute programmes, standards, procedures and internal controls to prevent and detect the offences defined in Law 50-88 of 30 May 1988 and its amendments. These programmes shall include, as a minimum:
  1. The establishment of procedures to secure a high standard of integrity among the staff and a system to assess personal background, career history and property status;
  2. Ongoing programmes of staff training, such as "know your client", and programmes covering the responsibilities outlined in Articles 8 and 10 of this Regulation;
  3. Include within the internal audit programme the programmes referred to in this article.
2. The financial institutions must also entrust management level officials with responsibility for monitoring compliance with the internal programmes and procedures, including the keeping of adequate records and the notification of suspect transactions. These officials will ensure liaison with the competent authorities.

## **ARTICLE 14 OTHER BINDING OBLIGATIONS**

1. When deemed appropriate, the tax administration will extend the application of the relevant provisions relating to financial institutions in this Regulation to economic transactions of any kind, where the transaction is made in cash and exceeds the national currency equivalent of US\$10,000, such as:
  1. The sale or transfer of roots, weapons, metals, artefacts, archaeological objects, jewellery, cars, ships, aircraft and other durable consumer goods, collectables or services related to travel or training courses;
  2. Casinos and other operations related to games of chance; or
  3. Professional services.

## **ARTICLE 15 OBLIGATIONS OF THE COMPETENT AUTHORITIES**

1. In accordance with law, the obligations of the Banking Superintendent shall include,
  1. Recommending to the Monetary Board the suspension or cancellation of licences or permits for the operation of financial institutions;
  2. Adopting the necessary measures to prevent and/or avoid any unsuitable person controlling or participating, directly or indirectly, in the direction, management and operation of a financial institution;
  3. Examining, monitoring or controlling the financial institutions and regulating and monitoring effective compliance with the registration and notification obligations established in this Regulation;
  4. Verifying by means of regular checks that the financial institutions are introducing and carrying out the compulsory programmes referred to in Article 13 of this Regulation;
  5. Supplying to other competent authorities the information obtained from financial institutions in accordance with this Regulation, including information derived from an examination of each of them when requested;
  6. Issuing guidelines or recommendations to help the financial institutions to detect suspect patterns of conduct among their clients.

These guidelines will be followed taking account of modern and reliable techniques in asset handling, and will be used as educational material for the

staff of the financial institutions;

7. Cooperating with the National Drug Control Directorate in the framework of investigations and proceedings concerning offences of illicit traffic or related offences.
2. The Banking Superintendent and the tax administration must communicate to the National Drug Control Directorate, within no more than seventy-two (72) working hours from the date on which they receive it, any information from financial or commercial institutions respectively concerning suspect transactions or activities which may be connected with offences of illicit traffic or related offences.
3. The Banking Superintendent and the tax administration, through the National Drug Control Directorate, must provide close cooperation with the competent authorities of other foreign territorial jurisdictions in investigations, proceedings and operations relating to offences of illicit traffic or related offences.

## **ARTICLE 16 INTERNATIONAL COOPERATION**

1. The court or competent authority shall cooperate with the court or competent authority of another State, taking appropriate steps in order to provide assistance in matters relating to an offence of illicit traffic or related offences, in accordance with the respective legal procedures and the rules of international law.
2. The court and the competent authority may make and receive requests from a court or competent authority of another State to identify, detect, seize or confiscate goods, products or instruments related to an offence of illicit traffic or related offences, as provided in Law 50-88 and its amendments.
3. A court order or judgment ordering the confiscation of goods, products or instruments, which is issued by a competent court of another State in connection with illicit traffic or related offences, may be admitted as evidence that the goods, products or instruments to which the order or judgment refers may be subject to confiscation in accordance with the legislation in force.
4. The court and competent authority may formulate, receive and take appropriate steps concerning a request from a court or competent authority relating to an investigation or criminal procedure concerning an offence of illicit traffic or related offences, or breaches of this Regulation. Such assistance may include the provision of originals and authentic copies of the relevant documents and records, obtaining testimony in the requested State, enabling voluntary attendance in the requesting State of persons required to make declarations, including persons in custody, the location or identification of persons, the delivery of summonses, the inspection of objects and places, the making of inspections and seizures, the provisions of information and evidence, and protective measures.
5. Legal provisions relating to banking secrecy or confidentiality shall not constitute an impediment to compliance with this article, when the information is requested via the Banking Superintendent and in accordance with international law.
6. Assistance in applying this article will be given in accordance with legislation.

### **Article 2.**

This Regulation derogates from and substitutes for Regulation no. 300-95, on offences and the laundering of assets relating to Illicit Traffic in Drugs and Controlled Substances of the Dominican Republic, of 17 December 1995. (3)

### **Article 3.**

For communication to the National Drug Control Directorate for the purpose of compliance.

GIVEN in Santo Domingo de Guzman, National District, Capital of the Dominican Republic, on the third (3rd) day of August one thousand nine hundred and ninety six, in the 153rd year of independence and the 133rd year of the Restoration.

Joaquin Balaguer

01

(1) Customs Cooperation Council nomenclature.

02

(2) Harmonized System of Customs Classification.

03

(3) Common international name published by the World Health Organization.

04

(\*) A substitute for permanganate.