Decree-Law No. 59/2006
of December 26

Medicinal products are vital in terms of health, the economy and society as a whole. Therefore, there is an acute need for up-to-date regulations on pharmaceutical activities.

More than 12 years after the introduction of the regulations contained in Decree-Law 3/93, of February 15, steps must be taken, as a matter of urgency, to update these rules and address their inherent inconsistencies and shortcomings, which prevent them from being fully implemented. The aim must be to modernize and update the entire legal framework governing medicinal products, from manufacture to marketing, always bearing in mind the need for and importance of evaluation and inspection activity, fundamental in ensuring the quality, safety and efficacy of medicinal products and for the protection of public health.

The aim of the present decree is, therefore, to establish more comprehensive and complete rules with regard to issues linked to the authorization of the marketing, registration, manufacture, importation, exportation, marketing, donation and advertising of medicinal products for human use.

Thus,

By way of the power afforded by Article 203 (2) (a) of the Constitution, the Government decrees the following:

CHAPTER 1

Aim, scope and definitions

Article 1

Aim

The present Decree shall govern the authorization of the marketing, registration, manufacture, importation, exportation, sale, donation, and advertising of medicinal products for human use.

Article 2

Scope

1. The present Decree shall apply to medicinal products for human use intended to be placed on the market in the form of generic drugs or proprietary medicinal products.
2. Medicinal products derived from human blood or plasma, immunological, radiopharmaceutical, homeopathic and herbal medicinal products, as well as those which may contain narcotic drugs and psychotropic substances shall be

subject to the provisions of this Decree, without prejudice to the provisions of special legislation.

Article 3

Definitions

For the purposes of the present Decree, the following definitions shall apply:

(a) Medicinal product: Any substance or association of substances presented as having curative or preventive properties with regard to human diseases or their symptoms, or which may be used or administered to human beings with a view to achieving a clinical diagnosis or, by performing a pharmacological, immunological or metabolic action, restore, correct or modify physiological functions;
(b) Proprietary medicinal products: Any ready-prepared medicinal product placed on the market under a special name and in an appropriate pack;
(c) Officinal formula: Any medicinal product which is prepared in accordance with the prescriptions of a pharmacopeia or an official formulary, in a dispensing pharmacy or in a hospital pharmacy service, to be supplied to a specific patient by that pharmacy or service;
(d) Magistral formula: Any medicinal product prepared extemporaneously in a dispensing pharmacy or hospital pharmacy service, in accordance with a medical prescription written by a doctor registered with the Doctors' Association, intended for a specific patient;
(e) Essentially similar medicinal products: Any medicinal products having the same qualitative and quantitative composition in terms of active principles and the same pharmaceutical form and which, where necessary, have been shown to be bioequivalent with the reference medicinal product, based on appropriate bioavailability studies;
(f) Reference medicinal product: A medicinal product whose active substance has been authorized on the basis of complete documentation, including results of pre-clinical and clinical pharmaceutical tests;
(g) International Nonproprietary Name (INN): Designation adopted or proposed at the international level, under the aegis of the World Health Organization (WHO) and in accordance with established procedures, for active substances of medicinal products, which cannot be registered as a trademark or name, in accordance with the list published by that Organization on a periodical basis.
(h) Generic name: Designation by which the active substance of a medicinal product is known, which does not correspond to an approved or recommended INN and is not registered as a trademark or name;
(i) Generic medicinal product (MG): A generic medicinal product shall be designated by its INN or, in the absence of an INN, its generic name, followed by the strength, the pharmaceutical form and the initials MG, which must be marked on the outer packaging of the medicinal product. The generic medicinal products must meet all the following conditions:

i. It must be essentially similar to a reference medicinal product already on the market and the respective active substances must be manufactured through processes that have fallen into the public domain or are protected by a patent held by the applicant or manufacturer or exploited with the authorization of the respective holder; and

ii. Claims should not be made regarding therapeutic indications different to those of the reference medicinal product.

(j) Active substance: Any material of human, animal, plant or chemical origin, to which is attributed an activity appropriate for a medicinal product;

(k) Pharmaceutical form: Final state of active substances following subjection to the necessary pharmaceutical operations, in order to facilitate their determination and achieve the maximum desired therapeutic effect;

(l) Product name: Designation of the medicinal product, which may consist of a trademark incapable of being confused with the INN, the INN accompanied by a trademark, or the name of the applicant or holder of the authorization, provided that no misunderstandings arise with regard to the therapeutic properties and nature of the medicinal product;

(m) Strength: Content of active substance expressed quantitatively per dosage unit, per unit of volume or weight according to the dosage form;

(n) Presentation: Dimension of the packaging taking into account the number of units;

(o) Immediate packaging: The container or other form of packaging immediately in contact with the medicinal product;

(p) Outer packaging: The packaging into which is placed the immediate packaging;

(q) Labeling: Information on the immediate or outer packaging;

(r) Package leaflet: written information intended for the user which accompanies the medicinal product;

(s) Medicinal product for hospital use: Medicinal product which, in accordance with the respective marketing authorization or national list of approved medicinal products and owing to its pharmacology, level of innovation, and on public health grounds, is exclusively reserved for use in hospitals;

(t) Wholesale marketing of medicinal products for human use: Commercial activity consisting in procuring, holding, storing or supplying medicinal products to be processed, resold or used by medical services, health units and pharmacies, apart from directly supplying medicinal products to the public;

(u) Wholesale trade establishment engaged in the trade in medicinal products for human use: Trade establishment whose main activity is the wholesale trade in medicinal products for human use;

(v) Advertising of medicinal products: Any form of communication, information, canvassing or incentive which directly or indirectly encourages the prescription, dispensing, sale, acquisition or consumption of medicinal products;

(w) Raw material: Any substance, active or inactive, regardless of origin, used in the manufacture of a medicinal product, which either remains unaltered, changes or disappears during the course of the process;

(x) Excipient: Any raw material which, including in its pharmaceutical forms, is added to active substances or their associates to serve as a carrier, enable those active substances or their associates to be prepared and stabilized, modify their organoleptic properties, or determine the physico-chemical properties of the medicinal product and its bioavailability;
(y) Pharmaceutical quality assurance: The total sum of the organized arrangements made with the object of ensuring that medicinal products are of the quality required for their intended use;
(z) Good manufacturing practice: The part of quality assurance designed to ensure that products are consistently produced and controlled in accordance with the quality standards appropriate to their intended use;

(aa) Donations: Offers or gifts of medicinal products made by foreign bodies or institutions to the public health structures, religious organizations and public-interest associations;

(bb) Adverse reaction: A reaction to a medicinal product which is noxious and unintended and which occurs at doses normally used in humans for the prophylaxis, diagnosis or treatment of disease or the recovery, correction or modification of physiological function;

(cc) Serious adverse reaction: An adverse reaction which results in death, is life-threatening, requires hospitalization or the extension of the period of hospitalization, results in significant disability or incapacity, is a congenital anomaly/birth defect;
(dd) Unexpected adverse reaction: An adverse reaction, the nature, severity, intensity or outcome of which is not consistent with the summary of the product characteristics;
(ee) Periodic safety report: The periodic and updated communication of safety information available at the international level regarding each medicinal product, accompanied by a scientific evaluation of the risks and benefits afforded by the medicinal product;
(ff) Post-marketing surveillance studies: Pharmacoepidemiological study or a clinical trial carried out in accordance with the terms of the authorization, conducted with the aim of identifying and investigating a safety hazard relating to an authorized medicinal product;
(gg) Abuse of medicinal products: Persistent or sporadic, intentional excessive use of medicinal products which is accompanied by harmful physical or psychological effects;
(hh) Risk-benefit evaluation: The evaluation of the positive therapeutic effects of a medicinal product in relation to the risks with regard to patient or public health and the safety, quality and efficacy of the medicinal product;
(ii) Urgent safety restriction: An interim change to information on the authorized medicinal product affecting the safety information included in the summary of the characteristics of the medicinal product, notably indications, posology, contra-

indications, warnings and adverse reactions, in light of new information concerning the safe use of the product;

(jj) Immunological medicinal products: Vaccines, toxins and serums, including, in particular, any product administered to produce active or passive immunity, as well as any product intended to diagnose, induce or reduce a specific hypersensitivity in the immunological response to an allergen agent;

(kk) Radiopharmaceutical product: Any medicinal product which, when ready for use, contains one or more radionuclides or radioactive isotopes included for a therapeutic purpose;

(ll) Medicinal products derived from human blood or human plasma: Medicinal products based on blood constituents, in particular, albumin, concentrates of coagulating factors and immunoglobulins of human origin;

(mm) Herbal medicinal product: Any medicinal product, exclusively containing as active ingredients one or more herbal substances or one or more herbal preparations, or one or more such herbal substances in combination with one or more such herbal preparations

Chapter II

Procedure for marketing authorization

SECTION I

General Provisions

Article 4

Authorization

1. The placing on the market of any medication, manufactured in Cape Verde or imported, requires the prior authorization of the General Directorate for Pharmacy (DGF), granted once the views of the National Medicinal Products Commission and the Agency for the Regulation and Supervision of Pharmaceutical and Food Products (ARFA) have been heard.

2. When a medicinal product has been granted a marketing authorization, any additional strengths, pharmaceutical forms, administration routes, additional presentations, as well as any variations and extensions that are granted authorization, shall be considered to be included in the marketing authorization already granted.

3. Medicinal products imported in accordance with Article 44 shall be exempt from the marketing authorization, the person responsible for their importation providing the DGF, within 90 days of the request, with a minimum of information on the medicinal product which must include the following elements:

a. A copy of the approval in the country of origin, if any.

b. Summary of product characteristics, package leaflet and packaging approved in the country of origin; and
c. Details of the manufacturer and a copy of the certificate of good manufacturing practice (GMP).

Article 5

Application

1. Marketing authorization shall be granted following an application by the interested party, addressed to the Director General of Pharmacy, which must contain the following elements:
   a. Name and address of residence or head office of the applicant;
   b. Name of technical director, the person responsible for the introduction of the product onto the market and who certifies the authenticity and veracity of the documents contained in the dossier;
   c. Proposed name of medicinal product;
   d. Pharmaceutical form and composition in terms of active substances, excipients, including strength, presentation, administration route, posology and shelf life;
   e. Therapeutic indication(s) established by the results of the clinical studies contained in the documents making up the dossier;
   f. Number of volumes in the dossier.
2. The application referred to in the preceding paragraph must be accompanied by the following documents;
   a. National marketing authorization request form;
   b. Summary of medicinal product characteristics which must be presented in the Portuguese language;
   c. Brief description of the manufacturing method and control tests employed by the manufacturer;
   d. Expert reports, referring to pre-clinical and clinical pharmaceutical tests, which must be in the Portuguese language, and which must state that the corresponding internationally recognized professional good practices were observed when obtaining said results.
   e. Environmental risk assessment report on the medicinal product, accompanied, where possible, by the proposed risk limitation measures;
   f. Draft label, packaging, outer packaging and package leaflet, which must be in the Portuguese language.
   g. Information sheet verifying the qualitative and quantitative composition of the product in terms of the active ingredients;
   h. Document demonstrating that the manufacturer is authorized to produce the proprietary medicinal product in his country; and
   i. Copies of the marketing authorizations of the medicinal product in other countries, as well as of decisions refusing authorization, including the respective grounds;
   j. Document attesting to payment of fee charged for the service.

3. The name of the medicinal product may be made up of an invented name or a trademark, the INN or generic name followed by the name of the manufacturer or brand.
4. In cases where the proposed product name is an invented name or a trademark, the INN shall be clearly marked.
5. Invented names or trademarks must not be liable to confusion with INNs, nor to create misunderstandings concerning the therapeutic properties and nature of the medicinal product.
6. The application shall be signed jointly by the applicant and the Technical Director.
7. Should the Technical Director also be the applicant, one signature shall be sufficient.
8. During the evaluation process, the DGF may require samples of the medicinal product in sufficient number to allow for the product to be analyzed, possibly repeatedly.

Article 6

Additional elements and clarification

The DGF may request the applicant to provide any additional elements and clarification considered necessary, failure to comply leading to the rejection of the application.

Article 7

Written information

1. The manufacturer, importer and/or distributor shall be responsible for the inclusion of information written in the Portuguese language on the characteristics and precautions to observe when using the medicinal product, without prejudice to this information being simultaneously provided in other languages.
2. The information referred to in the preceding paragraph must appear on the immediate and outer packaging and on the package leaflet referred to in Article 10 of this Decree, together with an explanation and details of the authorization process.
3. The information to be included under paragraph 1 shall be subject to prior verification by the DGF, in order to establish its veracity and suitability.
4. Alterations to labeling and package leaflets require the authorization of the DGF.
5. In cases of non-compliance with the present Decree, the applicant or holder of marketing authorization shall be notified in order to carry out the due corrections, a time period being set for this purpose.

6. Non-compliance with the provision contained in the preceding paragraph within the time period set shall lead to the suspension of the marketing authorization and consequent withdrawal from the market until the labeling and/or package leaflet of the medicinal product in question are in accordance with the provisions of the present Decree.

Article 8

Summary of product characteristics

1. The summary of product characteristics (referred to in Article 5 [2] [b]) shall include the following information:
   (a) The name of the medicinal product, followed by its strength and pharmaceutical form;
   (b) The pharmaco-therapeutic category;
   (c) The qualitative and quantitative composition in terms of active substances and excipients, knowledge of which is necessary for correct administration of the medicinal product. The INNs recommended by the World Health Organization (WHO), or, in the absence thereof, the common names or chemical descriptions shall be used.
   (d) Clinical particulars
      i. therapeutic indications;
      ii. contra-indications;
      iii. undesirable effects, frequency and seriousness;
      iv. special precautions for use;
      v. use during pregnancy or lactation;
      vi. interaction with other medicinal products and other forms of interaction;
      vii. posology and method of administration for adults and, where necessary, for children;
      viii. overdose, symptoms, emergency procedures, antidotes;
      ix. effects on ability to drive and to use machines.
   (e) Pharmacological properties
      i. pharmacodynamic properties;
      ii. pharmacokinetic properties;
      iii. preclinical safety data.
   (f) Pharmaceutical particulars
      i. list of excipients;
      ii. incompatibilities;
      iii. shelf life, after reconstitution of the medicinal product or when the immediate packaging is opened for the first time.
   (g) Name and address of marketing authorization holder or applicant;
   (h) Marketing authorization number(s);
   (i) Date of first authorization or renewal of the authorization;

(j) Date of revision of the summary of product characteristics; and

2. The summary of product characteristics shall be approved by the DGF and the applicant notified of this approval in accordance with Article 13.
3. The summary of product characteristics shall be kept permanently up to date, in accordance with the law, the marketing authorization holder presenting the appropriate applications for changes accordingly, on his own initiative or following a request by the DGF.

Article 9

Labels

1. The supply to the public of medicinal products wrapped in packaging which is not labeled in accordance with the provisions of this Decree shall be prohibited.
2. Outer packaging or, in the absence thereof, immediate packaging, must bear the following information in legible and indelible characters:
   a. the international non-proprietary name (INN);
   b. the qualitative and quantitative composition of the active substances per dosage unit, per unit of volume or weight determined according to the form of administration, including reference to the INN, where an INN for the medicinal product exists;
   c. the pharmaceutical form, presentation and strength;
   d. the method and route of administration;
   e. the shelf life, including month and year;
   f. the list of excipients, knowledge of which might be necessary for the appropriate use of the medicinal product. In the case of injectable products and topical and eye preparations, all excipients shall be indicated;
   g. production batch number;
   h. retail sale price;
   i. the phrase “Keep out of the reach of children”;
   j. name and address of residence or head office of the marketing authorization holder, manufacturer or importer;
   k. the printed phrases “Medicinal product subject to medical prescription”, “to be applied under clinical supervision only” (as the case may be) must appear in a clearly visible location;
   l. the shelf life after reconstitution of the medicinal product or when the immediate packaging is opened for the first time, where appropriate;
   m. specific storage precautions, where appropriate;
   n. special precautions for the destruction of unused products or residues derived from the medicinal products, where appropriate;
   o. the phrases “free sample” and “prohibited for sale to the public”, or other similar, where appropriate; and
   p. the phrase “external use”, printed on a red background, where appropriate;

q. the product's indication, in the case of medicinal products not subject to medical prescription;

3. In the case of ampoules, the indications provided for in the preceding paragraph must appear on the outer packaging, the inclusion of the following information on the immediate packaging being sufficient;
   a. name of the medicinal product;
   b. strength;
   c. method and route of administration;
   d. shelf life; and
   e. production batch number.
4. Packaging containing a unit dose on which it is not possible to mention all of the elements referred to in the preceding paragraph must bear the name of the medicinal product, strength and shelf life, with the information referred to in paragraph 1 of this Article appearing on the outer packaging.
5. Should there be more than one strength of the same medicinal product, in the same pharmaceutical form, the outer packaging shall point out the different strengths.

Article 10

Package leaflet

1. The aim of the package leaflet (PL) shall be to provide the patient with information concerning a specific medicinal product, with no reference being made to any other product.
2. The package leaflet must be written in the Portuguese language, in terms which are clear and legible for the patient, without prejudice to the information being simultaneously provided in other languages.
3. The inclusion of the package leaflet referred to in Article 5(2)(f) of this Decree in the packaging containing the medicinal product shall be compulsory, unless the information contained in that leaflet appears on the outer packaging or the immediate packaging.
4. As well as the information referred to in subparagraphs (a) to (d) and (g) of Article 8 (1), the package leaflet shall contain:

   a. average treatment time;
   b. instructions on what to do should one or more doses fail to be administered;
   c. information on how to stop the treatment if its suspension leads to discontinuation symptoms;
   d. specific storage precautions for medicinal products and information on visible signs of deterioration, should they exist;
   e. warning to the user to inform his doctor or pharmacist of any adverse affects detected which are not referred to in the package leaflet;
   f. warning to the user to check the shelf life;
   g. date of revision of PL.

5. The package leaflet may contain signs or images explaining certain information referred to in the preceding paragraph, as well as other information compatible with the summary of product characteristics and useful in terms of health education, excluding any kind of advertising.

Article 11

Laboratory checks

1. The DGF may require the person responsible for marketing to submit samples of the products at various stages of production, or of the finished product, to a recognized public or private laboratory for checks.
2. The DGF shall guarantee that the required checks will be carried out and the corresponding results communicated to the applicant within 90 days of receipt of the samples.

Article 12

Time periods

1. Marketing authorization shall be granted within a period of 180 days from the date of the request and 90 days in the cases provided for in Article 24.
2. The time period shall be suspended whenever, the process having yet to be completed, the applicant has been notified to correct any defects, or whenever additional elements or clarification have been requested.
3. In exceptional cases, the time period provided for in paragraph one may be extended for a period of 60 days, the applicant being informed accordingly prior to the end of the first time period.
4. Once authorization has been granted, the applicant shall have a period of 12 months, extendable only once, in duly justified cases, to introduce the medicinal product onto the market, after which time the authorization shall expire.

Article 13

Notification

1. The DGF must notify the applicant of the decision concerning the marketing authorization request, indicating, in the case of rejection, the respective grounds.
2. In cases in which authorization is granted, the DGF shall send the applicant a copy of the summary of product characteristics, package leaflet and labeling, in the terms in which they were approved.

Article 14

Registration of medicinal products

1. Granting of the marketing authorization request shall lead to the registration of the medicinal product.
2. Only three similar medicinal products may be registered for each medicinal product.

3. For public health reasons, the marketing authorization provided for by this Decree may be subject to certain special conditions, in particular with regard to the respective duration, compulsory nature of further tests, specific prescription conditions, possible restriction to certain specialized areas such as hospital use and special procedures for the communication of adverse reactions.

Article 15

Grounds for rejection

1. Applications for marketing authorization which do not fulfill the requirements and formalities contained in this Decree shall be rejected, in particular when:
   a. the dossier was not dealt with in accordance with the provisions of this Decree or contains mistakes;
   b. the medicinal product is harmful in the normal conditions of use, an evaluation having been carried out on the basis of information obtained from pharmacovigilance centers, or of statistically significant information concerning undesirable effects, which alters the risk-benefit balance;
   c. the therapeutic effect of the medicinal product has not been sufficiently proven;
   d. the qualitative and quantitative composition of the medicinal product is not the same as that declared;
   e. the effectiveness of the medicinal product (cost/benefit) has not been proven.
2. Appeals may be lodged in the case of rejections of applications for marketing authorization, in accordance with the legal provisions.

Article 16

Period of validity of authorization

The period of validity of the marketing authorization shall be five years, renewable for an indeterminate period, unless, for reasons of pharmacovigilance, it is decided to limit the additional renewal period to five years.

Article 17

Renewal of authorization

1. Requests for renewal must be presented by the interested parties up to 90 days prior to the end of the authorization.
2. The request for renewal must describe the situation with regard to the pharamacovigilance data and, where appropriate, must be accompanied by additional up-to-date documentation which demonstrates that the medicinal product previously authorized has been adapted to take into account technical and scientific advances.
3. The documentation to be submitted shall include:
    a. the request in written form;
    b. the renewal form;
    c. proof of payment of the fees referred to in Article 22;
    d. marketing authorization in the country of origin or, in its absence, equivalent authorization drafted in accordance with the WHO certification system; and
    e. Periodic Safety Report drafted in accordance with the international guidelines and standards in force.

Article 18

Suspension and refusal of renewal

1. The DGF may suspend marketing authorization, or refuse its renewal, in one of the following cases:
    a. In any of the circumstances provided for in Article 15(1)(b)-(e);
    b. The medicinal product presents a risk to public health;
    c. The information provided in the dossier accompanying the request for authorization is incorrect or contradicted by more recent information; and
    d. Non-compliance with the principles of good manufacturing practice.
2. The interested party shall be notified of the suspension and of the grounds for that measure, as well as of the time period for correcting any defects, failure to do so leading to the expiry of the marketing authorization.
3. The suspension and expiry of marketing authorization shall always lead to the withdrawal from the market of the respective medicinal product, within a time period established by the DGF, based on the grounds for suspension or expiry.
4. The marketing authorization holder shall be responsible for the withdrawal from the market referred to in the preceding paragraph.

Article 19

New authorization

1. The following alterations concerning medicinal products that have already been authorized shall require new authorization, to be granted within 120 days:
    a. name of medicinal product;

b. qualitative and/or quantitative composition of the active substances and excipients;
c. summary of product characteristics;
d. pharmaceutical form;
e. shelf life;
f. packaging material;
g. package leaflet; and
h. presentation.

2. The applicant shall present particulars, confirmed by experts specializing in the respective areas, supporting the application.

Article 20

Variations to the terms of a marketing authorization

The standards applicable to the procedure for requests for the variation of a marketing authorization, as well as the typology of those variations, shall be the subject of an Order of the Minister for Health.

Article 21

Confidentiality

The elements submitted for the preparation of dossiers referred to in the present Decree shall be confidential. All officials with knowledge of such elements shall be bound by secrecy.

Article 22

Fee

1. The marketing authorization request for each medicinal product shall be subject to the payment of a fee, set by a joint Order of the Ministers for Health and Finance.
2. The abovementioned fee shall be collected at the time of the submission of the request, independently of whether the request is granted or not.

SECTION II

Special Provisions

Article 23

Marketing authorization of generic medicinal products

Without prejudice to the provisions contained in Section I of this Chapter, marketing authorization of generic medicinal products shall be subject to the following details:

a. identification by means of the INN of the active substances or, in the absence thereof, the generic name, followed by the strength and pharmaceutical form;
b. waiving of submission of expert reports on pharmacological, toxicological and clinical tests; and
c. compulsory requirement to prove bioequivalence based on bioavailability studies or, should they prove to be inadequate, proof of therapeutic equivalence through appropriate clinical pharmacological studies.

Article 24

Recognition of marketing authorization granted by other States

1. The preparation of marketing authorization dossiers may be carried out through the recognition of a marketing authorization granted by another State.
2. The recognition of the abovementioned marketing authorization shall only be granted on the condition that the State which granted the authorization respects the following conditions:
    a. It has an official authority (service of the Ministry of Health of that State or a specialized service, such as an "agency" or "institute") which evaluates and authorizes medicinal products, observing, for this purpose, procedures, rules and standards recognized as components of an organization which guarantees the quality of the medicinal products introduced onto the market of the State in question; and
    b. It guarantees, through its inspection services, that the internationally recognized good manufacturing practices are effectively observed by the manufacturers.
3. Marketing authorization requests based on the recognition of a marketing authorization granted by another State, which meets the requirements contained in paragraph 2, may be submitted by the respective holder, through an application complying with the provisions of Article 5 (1).
4. Requests for recognition of marketing authorization must be accompanied by:
    a. a copy of the initial authorization and, should the State which granted the said authorization not be a Portuguese-speaking country, a Portuguese-language translation, duly authenticated by the competent authority;
    b. a copy of the last summary of product characteristics, approved in the country of origin and in the Portuguese language;
    c. should additions or alterations have been made to the original (such as, for example, new therapeutic indications, new undesirable effects, modification of posologies or of method of administration), the applicant shall make the corresponding declarations;
    d. declaration by the applicant stating that he shall immediately inform the DGF of any decision by the official authority(ies) of other States to

withdraw the medicinal product from one of the markets for which it was authorized;

e. declaration of the existence of marketing data, issued by the competent body of the country for whose marketing authorization WHO recognition or certification is being requested;

f. declaration to the effect that there has been no change to the risk/benefit balance, issued by the competent body of the country that granted the marketing authorization for which recognition is being requested; and

g. a list of safety alerts relating to the medicinal product, issued by the competent body of the country which granted the marketing authorization for which recognition is being requested, if any.

CHAPTER III

Manufacturing

Article 25

Authorization

1. Without prejudice to the competence of other departments of State, the manufacture of medicinal products shall be subject to prior authorization by the DGF.
2. Preparations made up in pharmacies for a specific patient shall be exempt from the provision contained in the preceding paragraph.
3. An appeal may be lodged in the case of refusal of the authorization provided for in paragraph 1, in accordance with the legal provisions.
4. The authorization provided for in paragraph 1 shall be attested to by the DGF through the issuing of a certificate, in accordance with the administrative provisions in force at WHO.

Article 26

Application

The request for authorization referred to in the preceding Article shall be formulated as an application containing the specification of the medicinal product, the pharmaceutical form to be manufactured, the place of manufacture and the existence of quality control capacity.

Article 27

Requirements

1. The manufacturing authorization provided for in this Decree shall be subject to the following requirements**:**
    a. the applicant must have available adequate installations and equipment, with the characteristics established under national legislation;
    b. there must be a full-time technical department;
    c. staff must be competent, qualified and in sufficient numbers to achieve the objectives of guaranteed pharmaceutical quality: and
    d. minimum capital of CVE 5,000,000 (five million Cape Verdean escudos) allocated to the activity, proof of which shall be provided through presentation of registration in the commercial register including the capital of the owner in sole proprietorship or partnership, or information on the owner/partnership's financial capacity provided by a credit or non-bank institution.
2. The requirements provided for in the preceding paragraph must be confirmed by the General Health Inspectorate and/or Inspection Service of the General Directorate of Pharmacy and ARFA.

Article 28

Technical directorship

1. Individuals carrying out the functions of technical director must have a degree in Pharmacy or in Pharmaceutical Sciences and at least five years' professional experience, duly recognized in Cape Verde.
2. In the case of marketing authorization holders who personally fulfill the requirements, they may assume the functions of technical director.

Article 29

Competences of the technical director

1. The technical director shall be responsible for all the pharmaceutical acts carried out as a part of the manufacturing process, including, in particular:
    a. compliance with the good manufacturing practices established by WHO.
    b. guaranteeing that each batch of medicinal products has been manufactured and controlled in accordance with the good manufacturing practices, following the methods and techniques included in the respective marketing authorization dossiers;
    c. implementing the quality policy with regard to the production and control phases;
    d. recording each product batch and preparing quality control reports, to be made available to inspectors for at least a year after the expiry of the batch;

e. checking to ensure that the active substances and other raw materials subject to processes of dividing up are analyzed in order to guarantee their quality and purity;
f. certifying that the records guarantee all possible protection against data falsification and ensuring that said records are kept;
g. ensuring the proper storage, packaging of medicinal products and raw materials, whether they be active or not;
h. guaranteeing compliance with the specific legal provisions governing narcotic drugs and psychotropic substances: and
i. introducing a procedure guaranteeing the recall of batches and a sufficiently rapid response in a given situation.

2. The liability of the technical director shall not exclude, in any case, the liability of the manufacturer.

Article 30

Time periods

1. Manufacturing authorization shall be granted within 120 days, starting from the date of the request.
2. The time period referred to in the preceding paragraph shall be suspended whenever additional information is requested, for the period fixed for compliance with the request.
3. Decisions relating to requests for the variation of an authorization shall be issued within 45 days of the submission of the request.

Article 31

Obligations of authorization holders

Manufacturing authorization holders shall be obliged to:

a. ensure that qualified staff are available to carry out manufacturing and quality control activities;
b. manufacture only those medicinal products for which they have authorization;
c. introduce a pharmacovigilance procedure for compilation and the notification of adverse reactions and events, in accordance with the technical guidelines drawn up by the DGF;
d. comply with the principles of good medicinal product manufacturing practice established by WHO and the respective manufacturing authorizations;
e. facilitate access for inspectors; and
f. comply with the other obligations provided for by law.

Article 32

Suspension and revocation

The DGF shall revoke or suspend manufacturing authorization in cases where any of the requirements deriving from the preceding Articles have not been observed.

Article 33

Variation

1. Requests for the variation of a manufacturing authorization, principally of some of the elements referred to in Articles 26 and 27, shall be decided on within a maximum of 30 days.
2. During the course of the time period referred to in the preceding paragraph, the DGF may, in exceptional and duly substantiated cases, decide to extend authorization for a period which may not exceed 90 days in total.

Article 34

Manufacture by third parties

Laboratories manufacturing pharmaceutical products may commission third parties to carry out all or certain phases of the manufacturing or control process provided for by this Decree, on the condition that they have been authorized to do so.

CHAPTER IV

Importation, exportation and marketing

SECTION I

Importation and exportation

Subsection I

General provisions

Article 35

Authorization

1. The importation and exportation of medicinal products for human use shall be subject to prior authorization by the DGF and only medicinal products

included on the National List of Medicinal Products, or listed on the register in Cape Verde, may be imported or exported.

2. Requests for authorization shall be made using the form contained in Annex I of the present Decree, the form being an integral part of the Decree on which the activities for which a license is being requested shall be specified.
3. The form shall contain information regarding the documents to be provided concerning each of the activities, along with the request for authorization, without prejudice to the fact that, in cases of the simultaneous request for authorization for more than one activity, only one copy shall be required for the processing of the authorization request.
4. As a minimum, each batch of imported medicinal products shall be submitted for qualitative and quantitative analysis with regard to the active substances, as well as for any other tests required to demonstrate their quality, in accordance with the respective marketing authorization.
5. Batches of medicinal products controlled in accordance with the requirements contained in the preceding paragraph must be accompanied by the control reports signed by the technician responsible.
6. The authorization provided for in paragraph 1 shall be certified by the DGF, taking into account the administrative provisions in force at WHO.

Article 36

Requirements

1. Authorization for the activities of importation and exportation of medicinal products shall be subject to the following requirements:
   a. the applicant must possess adequate installations and equipment;
   b. presentation of a draft manual of procedures for the area of activity;
   c. the presence of a pharmaceutical technician who shall, effectively and permanently, ensure and be responsible for compliance with the requirements specific to the area of activity; and
   d. minimum capital of CVE 5,000,000 (five million Cape Verdean escudos) allocated to the activity, proof of which shall be provided through presentation of registration in the commercial register including the capital of the owner in sole proprietorship or partnership, or information on the owner/partnership's financial capacity provided by a credit or non-bank institution.
2. The requirements provided for in the preceding paragraph must be confirmed by the General Health Inspectorate and/or the Inspection Service of the General Directorate of Pharmacy and ARFA.

Article 37

Application

1. The authorization provided for in Article 35 shall be granted following an application by the interested party, addressed to the Director General of Pharmacy, which shall include;
    a. details of the applicant (name);
    b. address of head office or residence;
    c. tax number;
    d. details of the pharmaceutical technical director responsible for the activity for which authorization is being requested; and
    e. location of the premises where the required activity is to be carried out.
2. Applications shall be accompanied by the following documents:
    a. document attesting to the Technical Director's qualifications;
    b. a statement of responsibility from the Technical Director and, where necessary, the statutes of the company which owns the premises where the activity in question is to be carried out;
    c. plan of the installations and equipment to be used for the activity, in order to ensure proper storage and marketing of the medicinal products; and
    d. police records of the Technical Director and partners.

Article 38

Processing of dossiers

The DGF shall be responsible for the processing of dossiers involving authorization of the activities of importation and exportation of medicinal products for human use.

Article 39

Inspection

1. Having checked that the application submitted is in order, the DGF shall plan the inspection of the installations where the applicant intends to carry out the activity. The inspection shall be carried out, at the applicant's request, by the Inspection Service of the DGF following payment of the previously prescribed fee.

2. The aim of the inspection is to check that the installations and equipment referred to in the documentation requested alongside the application comply with the requirement mentioned in Article 37 of the present Decree.

3. In the case of installations which do not meet the conditions contained in the preceding paragraph, the interested party shall have no less than 30 days to correct the defects identified.

Article 40

Time periods

1. The time period for the processing of the authorization request dossier by the DGF shall be 60 days, from the date of completion of the inspection.
2. The time period shall be suspended whenever the DGF requests the applicant to provide additional elements, or orders the correction of defects identified during inspection.

Article 41

Grounds for rejection

1. Requests for the authorization of the activities of importation and exportation of medicinal products shall be rejected should it be found that the applicant does not meet the requirements contained in the present Decree, or in the other applicable legislation.
2. Grounds for rejection shall consist, in particular, of:
    a. the lack of a pharmaceutical technical director; and
    b. the lack of installations which allow for medicinal products to be properly stored and marketed, in accordance with the requirements referred to in the "Good Marketing Practices".

Article 42

Notification

1. The DGF must notify the applicant of the granting or rejection of the request for authorization of the activities of importation and exportation of medicinal products for human use.
2. In cases of rejection, the respective grounds for that decision shall be clearly set out.

Article 43

Expiry of authorization

1. Authorization of the activities of importation and exportation of medicinal products for human use shall expire should the interested party;
    a. fail to begin the activity within six months of the date of the authorization; and
    b. suspend the activity for which the authorization was granted for a period of more than 6 months.
2. The time period provided for in subparagraph (a) of the preceding paragraph may be extended by the DGF once only, for an equal period of time, when duly substantiated by a written document addressed to the Director of the DGF.

Subsection II

Special Provisions

Article 44

Special importation

1. The Director General of Pharmacy may authorize the importation of medicinal products not marketed in Cape Verde, waiving the provisions of Articles 36 and 37, under the following conditions:
    a. when, through clinical justification, the products are considered to be vital to the treatment or diagnosis of specific pathologies;
    b. when the products are exclusively to be used for research and clinical trials.
2. Where appropriate, the provisions contained in the preceding paragraph shall also be applied to the importation of medicinal products based on the official WHO certification system.

Article 45

Exportation of medicinal products

1. The exportation of medicinal products shall not be subject to the provisions established in this Decree concerning packaging, labeling and presentation.
2. It shall be prohibited to export medicinal products which have been withdrawn from the market because they are considered to be harmful to public health;
3. For the purposes of exportation, the DGF must provide the summary of characteristics of the respective medicinal product in accordance with the terms under which it was approved.

SECTION II

Marketing

Subsection I

Wholesale marketing

Article 46

Authorization

1. The activity of wholesale marketing of medicinal products shall always require the authorization of the DGF, except in the circumstances laid out in the following paragraph.

2. Holders of a manufacturing authorization granted under the present Decree shall be exempt from the requirement to obtain the authorization provided for in the preceding paragraph for the marketing of medicinal products that they themselves have produced.
3. The authorization of the activity of wholesale marketing of medicinal products for human use shall not provide exemption from authorization for importation of medicinal products in cases where the products to be marketed are manufactured outside of the national territory.

Article 47

Requirements

1. Wholesale marketing authorization shall be subject to the following requirements:

    a. the applicant must have specialized installations for each specific step in the area of activity in question, as well as appropriate equipment, possessing the characteristics established in national legislation;
    b. there must be a permanent technical department, which must comply with the provisions of Article 28;
    c. in accordance with this Decree, there must be a procedure in place which establishes "Good Marketing Practices"
    d. minimum capital of CVE 4,000,000 (four million Cape Verdean escudos) allocated to the activity, proof of which shall be provided through presentation of registration in the commercial register including the capital of the owner in sole proprietorship or partnership, or information on the owner/partnership's financial capacity provided by a credit or non-bank institution.
2. The requirements provided for in the preceding paragraph must be confirmed by the General Health Inspectorate and/or the Inspection Service of the General Directorate of Pharmacy and ARFA.

Article 48

Application

1. Wholesale marketing authorization shall be granted following a request by the interested party, addressed to the General Directorate of Pharmacy, which must include:
    a. details of the applicant (name);
    b. address of head office or residence;
    c. tax number;
    d. details of the pharmaceutical technical director responsible for the activity for which authorization is being requested; and
    e. location of the premises where the required activity is to be carried out.

2. Applications shall be accompanied by the following documents:
    a. registration of the Technical Director with the Ministry of Health;
    b. a statement of responsibility from the Technical Director and, where necessary, the statutes of the company owning the establishment where the activity in question is to be carried out;
    c. plan of the installations and equipment to be used for the activity, in order to ensure proper storage and marketing of the medicinal products; and
    d. police records of the Technical Director and partners.

Article 49

Obligations of the authorization holder

Holders of authorizations to carry out the activity of wholesale marketing of medicinal products for human use shall be obliged to:

a. comply with the internationally-recognized principles of good marketing practice, approved at the national level;
b. maintain, at all times, a supply of medicinal products included on the National List, for each therapeutic class, in sufficient quantities to meet promptly the needs of the geographical territory determined at the time of the request for authorization;
c. keep records of all the transactions involving medicinal products going back at least five years;
d. only distribute those medicinal products with a marketing authorization and ensure that, at the time of their dispatch to the recipient, they are within their shelf life;
e. distribute the medicinal products exclusively to pharmacies, medicinal product sales points and public or private health bodies holding an authorization from the DGF, with direct sale to the public being prohibited;
f. refrain from distributing medicinal products which have been withdrawn from the market by order of the competent authorities;
g. facilitate access for inspectors to premises, installations and equipment;
h. notify the DGF in writing, accompanied by all the relevant information, of any significant modification of the installations or equipment initially authorized; and
i. notify the DGF of any adverse reaction reported concerning the medicinal products distributed.

Article 50

Records

1. The records referred to in subparagraph (c) of the preceding Article must include, at the very least, the following information:

a. date of transaction;
b. name, pharmaceutical form and presentation of the medicinal product;
c. quantity received or provided;
d. name and details of head office or residence of the supplier; and
e. details of the recipient.

2. The records required may be kept either in paper form or on computer, provided that it can be guaranteed that the data recorded cannot be falsified and that the legally required information will be safeguarded and kept.
3. The Technical Director shall be directly responsible for the establishment and regular updating of the records.

Article 51

Suspension, revocation and prohibition

1. The DGF must suspend the exercise of the activity of wholesale marketing in cases where the applicable legal standards and regulations are not observed.
2. The DGF may also suspend the exercise of the activity of wholesale marketing when the applicant has substantially modified the installations or equipment initially authorized without prior authorization.

Article 52

Regime

The activity of wholesale marketing of medicinal products shall be governed, with the necessary changes, by the provisions contained in the preceding section, in particular those contained in Articles 36-41.

Subsection II

Marketing regime

Article 53

Direct acquisition of medicinal products

1. Manufacturers, importers and wholesalers may only sell medicinal products directly to the following bodies:
   a. Pharmacies and medicinal product sales points;
   b. Public or private health establishments and services and non-profit making charities with medical and pharmaceutical services, provided that the products are to be used by those services.
2. Manufacturers, importers and wholesalers may freely trade in medicinal products between themselves.

Article 54

Sale to the public

Medicinal products may only be sold to the public in pharmacies and medicinal product sales points.

Article 55

Medical prescription

Medical prescriptions must identify the generic medicinal product by its INN or generic name, followed by the strength and pharmaceutical form.

Article 56

Non-prescription medicinal products

The DGF shall be responsible for determining which medicinal products may be sold without a medical prescription.

SECTION III

Technical Director

Article 57

Competences of the Technical Director

In the fields of importation, exportation and marketing, the Technical Director shall be responsible for all pharmaceutical acts carried out, including in particular:

a. compliance with good medicinal product distribution practices provided for by law, which shall necessarily be reflected in the written procedures;
b. checking that the medicinal products are included on the National List of Medicinal Products (LNM) and/or have a national marketing authorization;
c. guaranteeing that the medicinal products distributed comply with the legal requirements concerning presentation, notably information in the Portuguese language (packaging and package leaflet) and the presence of stamps;
d. recording each batch received, distributed and exported, guaranteeing their traceability and keeping those records available for inspectors for at least a year after the expiry of the batch;
e. maintaining an archive of copies or originals of the release certificates of each batch for at least a year after the expiry of the batch;

f. ensuring the proper storage, packaging of medicinal products and raw materials, whether they be active or not;
g. guaranteeing compliance with the specific legal provisions governing narcotic drugs and psychotropic substances;
h. introducing a pharmacovigilance procedure for compilation and notification of adverse reactions and events, in accordance with the technical guidelines drawn up by the DGF;
i. notifying the DGF of any absence and ensuring the presence of a replacement technical director.

CHAPTER V

Donations

Article 58

Appeal for donations

The following bodies may appeal for donations with the authorization of the DGF:

1. public health bodies;
2. religious organizations; and
3. non profit organizations.

Article 59

Requirements

1. All donations of medicinal products must be based on express needs and shall be in accordance with Cape Verde's morbidity.
2. The medicinal products may not be sent without the prior authorization of the recipient.
3. All donated medicinal products or their chemical equivalents must be on the National List of Medicinal Products.
4. The provisions contained in the preceding paragraphs shall be waived in the following situations:
   a. sudden outbreaks of diseases; and
   b. the appearance of a new pathology.

Article 60

Guarantee of quality and in-use storage time

1. All donated medicinal products must originate from a reliable source and comply with the international quality standards.

2. Donations may not include medicinal products that have already been used and returned, or free samples for health professionals.

3. At the moment of entry into Cape Verde of the donated medicinal products, these products must have an in-use storage time of a minimum of a year, unless they are destined for immediate delivery to health establishments, in which case, the health professional responsible shall issue an opinion concerning the shelf life of the medicinal products and the respective quantity.

Article 61

Presentation

1. The presentation, strength and formulation of the medicinal products donated must be analogous to those of the medicinal products used in the country.
2. The written information (summary of product characteristics, package leaflet and packaging) must be written in Portuguese, although the information may be simultaneously presented in other languages.
3. All packaging must bear the following information as a minimum:

    a. INN or generic name;
    b. batch number;
    c. pharmaceutical form;
    d. strength;
    e. name of manufacturer;
    f. shelf life; and
    g. quantity contained in the packaging.

CHAPTERVI

Advertising

Article 62

General principles

1. For the purposes of this Decree, advertising of medicinal products shall be considered to be any form of information, canvassing or incentive aimed at encouraging the prescription, dispensing, sale, acquisition or consumption of medicinal products:
    a. targeting persons qualified to prescribe or supply them;
    b. through visits by medical sales representatives to the persons referred to in the preceding subparagraph;
    c. through the supply of samples;
    d. through the gift, offer or promise of any benefit or bonus, whether in money or in kind, except when their intrinsic value is minimal;

e. through sponsorship of promotional meetings attended by the persons referred to in subparagraph (a);
f. through sponsorship of scientific congresses or meetings attended by the persons referred to in subparagraph (a), and in particular through payment, direct or indirect, of their travelling and accommodation expenses in connection therewith; or
g. through references to the brand name of a medicinal product.

2. advertising of medicinal products in the public media shall be prohibited.
3. advertising of medicinal products for which marketing authorization has not been granted shall be prohibited.
4. advertising may not deviate from the information contained in the summary of product characteristics, as authorized.
5. advertising must encourage the sensible use of medicinal products, doing so in an objective manner and without exaggerating the properties of the products.
6. advertising must be designed in such a manner as to ensure that the commercial message is clearly expressed, it being stated that the subject of the message is a medicinal product.
7. medicinal products may only be advertised in technical publications or audiovisual information material exclusively aimed at doctors and other health professionals.

Article 63

Prohibited advertising

1. Advertising of medicinal products may not contain any element which:
   a. leads people to conclude that medical consultation or surgery is unnecessary, in particular if a diagnosis is put forward or treatment by correspondence is proposed;
   b. suggests that the health of the patient may be affected should the medicinal product not be used, with the exception of vaccination campaigns;
   c. refers to a recommendation made by scientists or health professionals;
   d. leads to confusion of the medicinal product with a food product, cosmetics or any other consumer product;
   e. suggests that the safety or efficacy of the medicinal product is due to the fact that it is a natural product; and
   f. suggests that the medicinal product is guaranteed to have an effect and that there are no side effects.
2. All forms of comparative advertising shall be prohibited.
3. The free distribution of medicinal products to the public for promotional purposes shall be prohibited.

Article 64

Advertising material aimed at health professions

1. Advertising material targeting professionals licensed to prescribe or dispense medicinal products must include the following information as a minimum:
    a. Summary of product characteristics;
    b. Indication of the prescription, if any, or of the classification of the medicinal product for dispensing purposes; and
    c. The extent to which the price of the medicinal product is covered by the State.
2. The information contained in the document referred to in the preceding paragraph must be precise, up-to-date, verifiable and sufficiently complete to allow the recipient to form an accurate idea of the therapeutic value of the medicinal product.
3. Quotes and illustrative material taken from medical publications or scientific works destined to be used in the material provided for in paragraph 1, must be correctly reproduced and the respective source indicated.
4. Holders of marketing authorization or enterprises responsible for promoting the product must maintain a scientific service responsible for the information relating to the medicinal products they are putting on the market. Such services must hold all the scientific information relating to the medicinal products, and to the advertising activity carried out, in files which include details of the recipients, method and date of first instance of dissemination of information.

Article 65

Incentives

1. Those responsible for promoting medicinal products shall be prohibited from giving or promising, directly or indirectly, any benefit or bonus, whether in money or in kind, except when their intrinsic value is minimal.
2. Those prescribing or supplying medicinal products shall be prohibited from requesting or accepting any of the incentives provided for in the preceding paragraph.
3. The provisions of the preceding paragraphs shall apply without prejudice to the legally-established provisions concerning profit margins, prices and discounts.

Article 66

Free samples

1. Samples intended for the promotion of medicinal products may only be given to persons licensed to prescribe, under the following conditions:
    a. that they are the object of a request made by the recipient;
    b. that they shall be identical to the smallest marketing presentation.
2. They shall bear the phrases “free sample”, “not for sale to the public”, or similar;
3. They shall be accompanied by a copy of the summary of product characteristics;

4. Samples of medicinal products containing narcotic drugs or psychotropic substances may not be given out.

Article 67

Scientific and professional events and actions promoting medicinal products

1. Sponsorship by the holder of the marketing authorization, or the enterprise responsible for the promotion of a medicinal product, of actions promoting medicinal products, training and scientific events, such as congresses and symposiums, must be referred to in the promotion material concerning the medical products, as well as in documents concerning the participants and in the works or reports published prior to such events or actions taking place.
2. The holder of the marketing authorization, or the enterprise responsible for the promotion of a medicinal product, must keep the documentation referring to each of the events or actions they have sponsored and that are referred to by this Article with the service referred to in paragraph 1 of the preceding Article for a period of five years and in a form that facilitates inspection at any moment by the competent public services.
3. The abovementioned documentation must contain the following elements, reproduced faithfully and completely:
    a. the program of actions and events;
    b. the details of the body carrying out, sponsoring and organizing the actions and events;
    c. copies of the scientific or professional communications released.

Article 68

Civil liability

1. The advertisers, advertising agencies and any other bodies carrying out advertising activity, as well as the holders of the advertising media used or the respective concession holders, shall have joint and civil liability, under general terms, for prejudice caused to third parties as a result of the broadcast of illegal advertising messages.
2. The advertisers shall be exempt from the liability provided for in the preceding paragraph should they be able to prove that they did not have prior knowledge of the message delivered.

CHAPTER VII

Inspection

Article 69

Competence

Verification of compliance with the rules contained in this Decree shall lie within the competence of the General Health Inspectorate and/or the Inspection Service of the General Directorate of Pharmacy and ARFA.

Article 70

Duty of information

Bodies authorized to carry out the activities within the scope of this Decree shall be obliged to present the General Health Inspectorate and/or the Inspection Service of the General Directorate of Pharmacy and ARFA with any information they may request.

Article 71

Inspection Activity

1. Inspections may be carried out, at any time, of enterprises, establishments or premises where medicinal products are to be found, including narcotic drugs or psychotropic substances, and the presentation of documents or records relating to said products may be requested.
2. For the purposes of the preceding paragraph, the General Health Inspectorate and/or Inspection Service of the General Directorate of Pharmacy and ARFA may request the support of appropriate national or foreign bodies or experts.
3. Prior to inspection, officials shall identify themselves by means of ID cards or credentials issued by the General Health Inspectorate and/or the General Directorate of Pharmacy or ARFA, bearing reference to their power to carry out inspections.
4. Should the body being inspected refuse to present the documents or records and prevent inspection of the premises, the local police shall be requested to cooperate in carrying out the task.
5. In the interests of coordination, the body or authority carrying out the inspection shall inform the other bodies of this fact, as well as providing them with the results and respective reports.
6. Following each inspection, a written report shall be prepared and filed with the respective service, unless it forms a part of criminal proceedings.

Article 72

Quality control of medicinal products

1. The necessary quality control analyses shall be carried out at the national laboratory for the quality control of medicinal products, without prejudice to the fact that, under the protocols signed, they may be carried out abroad.

2. For the purposes set out in the preceding paragraph, the General Health Inspectorate and/or Inspection Service of the General Directorate of Pharmacy, or ARFA may collect samples of the medicinal products (in their finished state or at any stage of production), as well as of the respective raw materials and packaging materials.
3. The provisions of this Article shall cover medicinal substances, cosmetics, products intended for the purposes of hygiene and/or prophylaxis and others whose verification may be deemed appropriate by the Inspectorate.

Article 73

Seizure of unauthorized medicinal products

1. Medicinal products put on sale without the necessary authorization shall be seized by the General Health Inspectorate and/or the Inspection Service of the General Directorate of Pharmacy, or ARFA.
2. The medicinal products seized may not be used or be used in public health bodies, upon proof of their quality.

Article 74

Inspection of medicinal products in transit

Inspection activity may be carried out whenever deemed necessary, including with regard to medicinal products in transit.

Article 75

Duty of cooperation

Owners, directors, their representatives and workers at establishments dedicated to the manufacture, storage and marketing of medicinal products, shall be obliged to:

a. facilitate the entry of all duly identified agents responsible for inspection into their premises, establishments and offices, for the period deemed necessary;
b. present these agents with the documentation, accounting records, registers, archives and other elements which may be requested and, also, to provide any information and statements requested.

Article 76

Correction of defects

In cases in which the inspected bodies have not complied with the legal provisions, without prejudice to any sanction arising from the case, the competent bodies may, in

accordance with Article 69, grant a reasonable time period for the correction of the defects identified.

CHAPTER VIII

Offenses

Article 77

Infringements and fines

1. Without prejudice to criminal, disciplinary or civil liability or administrative sanctions and measures which may be applied, infringements of the provisions of this Decree shall constitute offenses punishable in accordance with the terms of the following paragraphs.
2. The falsification of medicinal products or substances, as well as the sale, acquisition or transport and/or storage for the purposes of marketing, of said medicinal products or substances, shall constitute an offense, punishable with a fine of CVE 500,000 to CVE 1,000,000.
3. The violation of the provisions of Articles 62 and 63 shall constitute an offense, punishable with a fine of CVE 100,000 to CVE 200,000, which may be applied along with the additional penalty of the suspension, for up to two years, of advertising of the medicinal product.
4. The following shall constitute offenses punishable with a graduated fine of CVE 500,000 to CVE 2,500,000 or up to CVE 5,000,000, depending on the nature of the agent, i.e. natural or legal person:
    a. the exercise of the activity of the manufacturing of medicinal products for human use without prior authorization;
    b. the importation into Cape Verde of medicinal products that are out of date for marketing purposes;
    c. the violation of the duty of public service in terms of the production of quality medicinal products; and
    d. the manufacture of medicinal products lacking the corresponding marketing authorization and/or not included on the National List of Medicinal Products;
5. The following shall constitute offenses punishable with a fine of CVE 200,000 to CVE 1,000,000 or up to CVE 2,000,000, depending on the nature of the agent, i.e. natural or legal person:
    a. the violation of the duty to ensure the presence of an effective and permanent technical department at the authorized establishment;
    b. the violation of the principles and standards of good manufacturing practice;
    c. the violation of the standards relating to the recording of production and quality control operations; and
    d. the marketing of medicinal products manufactured by bodies lacking legal authorization;

6. The following shall constitute offences punishable with a fine of CVE 200,000 to CVE 1,000,000 or up to CVE 2,000,000, depending on the nature of the agent, i.e. natural or legal person:
   a. the exercise of the activity of wholesale marketing of medicinal products for human use without prior authorization;
   b. the wholesale marketing of medicinal products without the necessary marketing authorization, and/or of medicinal products not included on the National List of Medicinal Products, or of medicinal products whose withdrawal from the market has been ordered by the competent authorities; and
   c. wholesale marketing to persons or bodies lacking legal authorization.
7. The following shall constitute offenses punishable with a fine of CVE 100,000 to CVE 500,000 or up to CVE 1,000,000, depending on the nature of the agent, i.e. natural or legal person:
   a. the violation of the duty to ensure the presence of an effective and permanent technical department at the authorized establishment;
   b. the violation of the principles and standards of good marketing practice;
   c. the violation of the standards relating to the recording of medicinal product transactions;
   d. the marketing of medicinal products, the shelf life of which has already expired on the date of their delivery to the recipient; and
   e. the marketing of medicinal products without the respective stamps.
8. The technical director of the establishment shall be sanctioned as the co-author of the offenses referred to in paragraphs 5 and 7.

Article 78

Application

1. The application of sanctions shall lie within the competence of the competent bodies provided for in Article 69, except in the case provided for in the following paragraph.
2. The application of the sanction of the closure of the installations of the distributor and manufacturer, as well as the prevention of the conduct by the technical department of its activities, shall be within the competence of the Ministry of Health.

Article 79

Distribution of money collected through fines

The money collected as fines shall be distributed in the following manner:
   a. 40 per cent for the Public Treasury;
   b. 40 per cent for the services of the DGF; and
   c. 20 per cent for the body applying the fine.

Article 80

Appeals

In accordance with the law, *despachos punitivos* (documents summing up the offense and sanctions to be applied) shall be open to appeal to the administrative authority or to the administrative courts.

Article 81

Remaining cases

All cases of violation of this Decree not specifically provided for shall be punished with fines from CVE 10,000 to CVE 80,000.

Article 82

Negligence and attempted violations

Negligence and attempted violations shall always be punishable.

CHAPTER IX

Final and transitional provisions

Article 83

Medicinal products included on the current National List of Medicinal Products

Medicinal products included on the National List of Medicinal Products, be they manufactured locally or imported, shall be subject to a request for marketing authorization, within the time period set by the DGF.

Article 84

Costs

The costs of the acts relating to the procedures provided for in this Decree and of the laboratory tests shall be met by the applicants, the rates being set by an Order of the Ministers of Health and Finance.

Article 85

Notifications

The notifications to the applicants referred to in this Decree must be sent by registered post.

Article 86

Entry into force

This Decree shall enter into force 180 days after publication.

Article 87

Revocation

Decree-Law 3/93, of February 15, is hereby revoked

Seen and approved in the Council of Ministers:

José Maria Pereira Neves - Basílio Ramos - Cristina Duarte - João Pereira Silva

Promulgated on December 15, 2006

Let it be published

The President of the Republic