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In the sphere of action of the Health Policy, medications assume a particular relevance for the benefits they produce, as well as for the costs they originate, constituting a decisive weapon in the treatment and in the prevention of the most frequent illnesses, particularly within the area of primary health care.

It becomes, then, necessary to create a judicial framing that allows adapting the pharmaceutical sector to the country's needs. In this sense, the diploma now published is part of a legislative package, having already published the decree-law n. 92/92 of July 20, relative to the control of illicit market of narcotics, psychotropic and traversing substances, and foreseeing, the approval by the Government, in the near future, of the diploma that regulates the property, licensing and operation of the pharmacies.

The publication of the present diploma constitutes a decisive step towards the modernization of the pharmaceutical sector's management, with the purpose of improving the capeverdean population's life quality, guaranteeing a safer and more rational access to the medications, which constitute one of the corner-stones of the health policy.

Thus:

Using the faculty conferred by paragraph *a),* point 2 of Article 216 of the Constitution, the Government decrees the following:

CHAPTER I
General dispositions

Article 1
(Objective)

This diploma establishes the rules that must be followed in order to authorize the introduction in the market, the registration, the manufacturing, the importation, the exportation and the commercialization of medications.

Article 2
(Scope)

1. The present diploma applies to the medications for human usage destined to be placed in the market under the form of generics or pharmaceutical specialties.

2. The medications in whose composition there are narcotics and psychotropic substances are subject to the provisions of this diploma, without loss for the regulations in special legislation.

3. The medications for veterinary usage are object of a very diploma.

Article 3
(Definitions)

For the purposes of the present diploma:

a) Medication: is all substance or mixture of substances, destined to be administered to men or to animals in the treatment or prevention of the illnesses and their symptoms, in the correction or modification of physiologic functions or in view to establish a medical diagnostic;

b) Pharmaceutical specialty: is every medication prepared beforehand and introduced in the market under a commercial denomination and appropriate conditioning.

CHAPTER II
Introduction in the market

SECTION I
Processing

Sub-section I
Common provisions

Article 4
(Authorization)

1. The introduction of any medication in the market, fabricated in the country or imported, needs previous authorization of the General Administration

of Pharmacy, farther along designated DGF, through technical advice of the National Commission of Medications.

2. The authorization of introduction in the market, farther along designated AIM, mentioned in the previous number, can only fall on the medications included in the National List of Medications.

Article 5
(Request for AIM)

1. The request for AIM is addressed to the General Director of Pharmacy, by the concerned person, and must contain:

a) Name or social designation and domicile or headquarters of the petitioner;

b) Proposed name for the medication;

c) Pharmaceutical form and composition in what concerns active substances, excipients, including dosage, presentation and way of administration;

d) Therapeutic indication;

e) Number of volumes that constitute the process;

2. The petition mentioned in the previous number must be instructed with the following documents:

a) Summary of the characteristics of the medication;

b) Summary descriptions of the preparation mode;

c) Scientific documentation constituted by the descriptions of the control methods used and by the results of the physical-chemical, biologic, microbiologic, toxicological, pharmacologic and clinical tests.

d) Reports from the experts;

e) Projects of the label, container, external package and informative prospectus;

f) Samples of the medication in sufficient number for its analysis and eventual repetition and confirmation;

g) Analytical bulletin of the verification of its qualitative and quantitative composition in respect to the active principles;

h) Document that demonstrates that the producer is authorized to produce the pharmaceutical specialty in his country.

Article 6
(Summary of the medication's characteristics)

The summary of the characteristics mentioned in subparagraph *a)*, point 2, of the previous Article, must contain the following indications:

a) Denomination of the medication;

b) Qualitative and quantitative composition in active substances, and constituent of the excipients whose knowledge is necessary for a good administration of the medication, and the common international denominations recommended by the World Health Organization must be utilized, or in their absence, the common denominations or the chemical denominations;

c) Pharmaceutical form;

d) Pharmacological properties and, insofar they are useful, the therapeutic utilization and the pharmacy kinetics elements;

e) Therapeutic indications;

f) Counter indications;

g) Undesirable effects, frequency and gravity;

h) Special utilization precautions;

i) Utilization in case of pregnancy or lactation;

j) Medicinal interactions and others;

l) Posology and administration mode for adults and, when necessary, for children;

m) Excessive dosage, symptoms, urgent measures, antidotes;

n) Special precautions;

o) Effects over driving capacity and utilization of machines;

p) Major incompatibilities;

q) Duration of stability after reconstitution of the product or when the container is open for the first time;

r) Particular conservation precautions;

s) Nature and content of the container;

t) Name or social designation and domicile or headquarters of the petitioner;

u) Precautions for the elimination of the products not utilized or the residuals derived from those products, in case they exist.

Article 7
(Laboratorial control)

The DGF may require that the person responsible for the introduction in the market submit samples of the products in different manufacturing phases or the finished product to the control of a public or private lab, of recognized idoneity.

Article 8
(Deadlines)

1. The AIM will be granted 120 days from the date of the petition;

2. The deadline is suspended whenever, being the process incomplete, the petitioner is notified to make up for the deficiencies.

3. In exceptional case, the deadline provided for in number 1 may be postponed for a period of 60 days, and the petitioner must be notified before the end of the first deadline:

4. Once the authorization has been granted, the petitioner has twelve months, postponable for equal period when duly justified, to introduce the medication in the market. At the end of this period of time, the authorization expires.

Article 9
(Notification)

The DGF must notify the petitioner that he has been authorized to introduce the medication in the market, sending him a copy of the summary of the medication's characteristics, under the terms it has been approved, and the information prospect.

Article 10
(Rejection)

1. The AIM request must be rejected when it doesn't satisfy the requisites and formalities required in the present diploma, and mainly when:

a) The medication is harmful, under normal conditions of employment;

b) The therapeutic effect of the medication is insufficiently verified;

c) The medication doesn't have the declared qualitative and quantitative composition.

2. The rejection and the respective justification must be notified to the petitioner, and the same is susceptible to be appealed under legal terms.

Article 11
(Validity of the authorization)

The AIM is valid for five years, renewable for equal periods.

Article 12
(Renewal of the authorization)

1. The request of renewal must be presented by the concerned person until 90 days before the term of the authorization.

2. The renewal request, when it's the case, must be accompanied by complementary updated information, which demonstrates the adaptation to the technical and scientific progress of the medication previously authorized, when so is the case.

Article 13
(New authorization)

1. The following alterations of medications already authorized need a new authorization:

a) Name of the medication;

b) qualitative and/or quantitative composition of the active substances and excipients;

c) Summary of the medication's characteristics;

d) Pharmaceutical form;

e) Time of validity;

f) Container's material;

g) Information prospect;

h) Presentation.

2. In case provided in the previous number, the petitioner must present justificatory elements confirmed by specialized technicians of the respective fields.

Article 14
(Suspension and refusal to renew)

1. The DGF may, after consulting the National Commission on Medications, suspend the AIM, or deny its renewal, when:

a) The medication turns out to be harmful to health;

b) When it is verified that the medication doesn't have the announced therapeutic effect;

c) The medication doesn't have the declared qualitative and quantitative composition;

d) It becomes necessary to ensure the protection of public health;

e) It is ascertained that the indications provided in the process that are attached to the request for authorization are erroneous or new discoveries go against them;

f) The norms about labeling provided for in this diploma are not observed.

2. The suspension, as well as its justifications is notified to the concerned person, with indication of a deadline to correct the deficiencies, under penalty of caducity of the AIM.

3. The suspension and caducity of the AIM always imply the withdrawal of the respective medication from the market.

4. The withdrawal from the market mentioned in the previous number is the responsibility of the holder of the AIM.

Article 15
(Secrecy)

The elements presented to DGF for the instruction of the proceedings mentioned in the present diploma are confidential and the employees that take notice are subject to the duty of secrecy.

Article 16
(Medications Registration)

1. The authorized medications must be registered in the DGF.

2. Only three equivalent products can be registered for each medication.

3. The registration of each medication is subject to the payment of a fee which will be fixed by joint decree of the Government members, in charge of the Health and Finances sectors.

4. The medications imported under the terms of Article 28 are exempted of registration;

SUBSECTION II
Special provisions

Article 17
(AIM of generic products)

For the purpose of the present diploma, the medications that cumulatively gather the following conditions are considered generic products:

a) To be essentially similar to a medication already introduced in the market and the respective active substances fabricated by processes fallen in the public domain, or protected by patent owned by the petitioner or explored by him, with the respective authorization of the owner.

b) Not to invoke in their favor different therapeutic indications relatively to the essentially similar medication already authorized.

Article 18
(AIM of generic products)

Without loss for the provision in subsection I of this chapter, the AIM of generic products is subject to the following specificities:

a) Identification by the common international denomination of active substances or, in its absence, by the generic name , followed by the dosage and pharmaceutical form;

b) Exemption of presentation of reports by the experts about the pharmacological, toxicological and clinical trials;

c) Obligatoriness of the demonstration of bioequivalence based on studies of bioavailability or, when these are not adequate, of the demonstration of therapeutic equivalence through appropriate pharmacological studies.

Article 19
(Medical prescription)

The medical prescription must identify the generic product by the common international denomination or by generic name, followed by the dosage and pharmaceutical form.

CHAPTER III
Manufacturing, Importation, Exportation and Commercialization

SECTION I
Manufacturing

Article 20
(Authorization)

1. Without loss for the competences of other State departments, the manufacturing of medications is subject to prior authorization by the General Director of Pharmacy.

2. Exceptions to the previous number are the preparations, when made in pharmacies and destined to a certain patient.

3. The denial of authorization provided for in number 1, can be appealed.

4. The authorization provided for in number 1 may be certified by DGF, taking into account the administrative provisions in force in the World Health Organization.

Article 21
(Petition)

The petition for authorization mentioned in the previous article is formulated on an application that consists of the medication's specification, pharmaceutical form to fabricate, the place of manufacturing and the existence of quality control capacity.

Article 22
(Requisites)

1. The authorization for manufacturing provided for in this diploma is subject to the following requisites:

a) The petitioner must have the adequate installations and equipment and with characteristics established in appropriate legislation:

b) To have a Technical administration.

2. The requisites provided for in the previous number must be object of confirmation by the General Inspection of Health.

Article 23
(Deadlines)

1. The authorization for manufacturing is granted within 90 days from the date of the petition.

2. The deadline mentioned in the previous number is suspended whenever complementary information is requested and for the time fixed for their fulfillment.

3. The decision relative to the request of alteration of the authorization is pronounced within 30 days from the date of the petition, at the end of which it's presumed authorized.

Article 24
(Obligations of the authorization holder)

The holder of the authorization for manufacturing is obligated to:

a) Follow the norms of the good practices of medication manufacturing provided for in the law;

b) To facilitate the access to the inspection agents;

c) To observe the other obligations provided for in the law.

Article 25
(Manufacturing by others)

The pharmaceutical products labs may entrust to others the execution of the totality or certain phases of the manufacturing or control provided for in this diploma, if they are so authorized.

SECTION II
Import and export

Article 26
(Authorization to import)

1. The import of medication needs to be authorized by the DGF and can only fall on medications included in the National Medications List.

2. The provisions of Article 22 and 23 are applicable to the medication imports.

Article 27
(Special imports)

1. The General Director of Pharmacy may authorize the import of non commercialized medications with exemption in the Article 22's provisions, in the following conditions:

a) When through clinical justification, are considered indispensable for the treatment or diagnostic of certain pathologies;

b) When they are exclusively destined to research and clinical trials.

2. When it is convenient, the previous number's provision will apply equally to the imports of medications that are based on the WHO's official certificate system.

Article 28
(Export of medications)

1. The export of medications is not subject to the provisions established in this diploma in regard to packing, labeling and presentation.

2. The export of medications that have been withdrawn from the market is forbidden because they considered harmful to the public health.

3. The DGF must provide, for export purposes, a summary of the characteristics of the respective medication under the terms it was approved.

SECTION III
Commercialization

Article 29
(Price regime)

The regime of medications' prices is fixed by joint decree of Government members in charge of Health, Industry and Commerce sectors.

Article 30
(Direct acquisition of medications)

1. The producers and importers may sell medications directly to the following entities:

a) Pharmacies and sale stations;

b) Public and private health establishments and services and non lucrative solidarity institutions that dispose of a medical and pharmaceutical service, provided that the medications are destined to their own consumption.

2. The producers and importers may freely transact medications among themselves.

Article 31
(Sale to the public)

The medications can only be sold to the public in pharmacies and medication stations.

Article 32
(Free sale medications)

1. Free sale medications are those that, being destined to the treatment or prevention of certain illnesses, can be acquired without a medical prescription because they don't require medical care.

2. It belongs to the DGF to determine which ones are free sale medications.

CHAPTER IV
Technical Direction

Article 33
(Technical direction)

1. The holder of the manufacturing and import authorization must permanently dispose of a technical direction.

2. In order to perform the technical director functions it is necessary to have a license in Pharmacy and Pharmaceutical Sciences and an adequate professional qualification, properly recognized in the country.

3. In case the authorization holder personally fills the requisites, he may accumulate the functions of technical director.

4. The responsibility of the technical director doesn't exclude, in any case, the responsibility of the manufacturer.

Article 34
(The technical director's competences)

The technical director is responsible for all the acts practiced within the scope of manufacturing and import, being incumbent on him, namely:

a) To guarantee that each lot of medications has been manufactured and controlled in accordance with the norms of manufacturing good practices, following methods and techniques appear in the respective authorization file.

b) To register each manufactured lot and elaborate the quality control reports, making himself available to the inspection agents, during at least one year after the caducity of the lot;

c) To make an effort so the active substances and other raw materials subject to division operations are analyzed, in view to guarantee their quality and purity;

d) To zeal for the warehousing, conditioning of the medications and active raw materials, or not;

e) To guarantee the observance of the specific legal provisions that regulate the narcotics and psychotropic substances.

CHAPTER V
Labeling, information prospect and publicity

SECTION I
Labeling

Article 35
(Written information)

1. The manufacturer and the importer are responsible for the inclusion on the label mentioned in subparagraph *e)*, point 2, Article 5 of this diploma, of information, written in Portuguese, about the characteristics and precautions to observe in its usage, without loss for the simultaneous provision of that information in other languages.

2. The information mentioned in the previous number must appear in the external package, on the container and on the information prospect mentioned in Article 37 of this diploma, with the development and the specifications included in the authorization file.

Article 36
(Labels)

1. The external package or, in its absence, the container must have in readable and permanent characters, the following indications:

a) Generic name;

b) Qualitative and quantitative composition of the active substance by unity of taking, volume or weight determined according to the form of administration, utilizing the common international denominations whenever they exist;

c) Pharmaceutical form and respective content in weight, volume or unity number;

d) Mode and canal of administration;

e) Validity period, including month and year;

f) List of the excipients whose knowledge is eventually necessary for the convenient utilization of the medication;

g) Registration number of the authorization to introduce the medication in the market;

h) Manufacturing lot number;

i) Sale price to the public;

j) The expression «keep out of reach of children»;

l) Name and social designation and domicile or headquarters of the AIM holder, manufacturer or importer;

m) The expressions printed on a visible spot, «can be sold only with medical prescription», «Can be applied only under medical supervision», depending on the cases;

n) Utilization deadline after reconstitution of the medication or opening for the first time of the container, if such is the case;

o) Particular conservation precautions, if such is the case;

p) Special precautions for the destruction of the products not utilized or the residuals derived from the medications, when so are the cases;

q) The expressions «free sample» or «Prohibited the sale to the public» or other similar expressions, when so is the case;

r) The expression «external use», printed on red background, when so is the case;

s) The expression «veterinarian use» printed on green background, if such is the case.

2. In case of vials, the indications provided in the previous number must appear on the external package, being sufficient the following indications on the container:

a) Name of the medication;

b) Quantity of active substances by pharmaceutical form;

c) Mode and canal of administration;

d) Validity;

e) Number of manufacture lot.

3. The small vessels containing a unitary dose in which it is not possible to mention all the references provided in the previous number must contain the medication's name, the quantity of active substances and the validity period, showing on the external package the indications mentioned in point number one of this Article.

4. In the absence of an external package, the indications mentioned in point 1 of this Article must appear on the container.

5. In case there is more than one dosage of the same medication in the same pharmaceutical form, the external package will obligatorily have the reference f the different dosages.

SECTION II
Information prospect

Article 37
(Information prospect)

1. The information prospect is designed to inform the patient, and must concern one medication only, and may not make reference to other medications.

2. The inclusion of the information prospect mentioned in subparagraph *e),* point 2, Article 5 of this diploma is obligatory on the package that contains the medication, except if the information conveyed by it appears on the external package or on the container.

3. Besides the indications mentioned in the previous Article, point 1, *a), b), c), d), f), l), o) and p)*, the information prospect must contain the following:

a) Therapeutic indications;

b) Counter indications, most frequent or serious side effects, and actions to be taken when they occur;

c) Medicinal interactions and others;

d) Special utilization precautions;

e) Pharmaco-therapeutic categories;

f) Effects in pregnant women, sucking babies, children, aged people and patients with special pathologies;

g) Effects over driving capacity and machines operation;

h) Usual posology with reference t the maximum dosage;

i) Indication of the most favorable moment for its administration;

j) Duration of an average treatment;

l) Instructions about what to do when the patient skips one or more dosages;

m) Indication of how to stop the treatment if its suspension causes privation effects;

n) Particular precautions of conservation of medications and indication of visible signs of deterioration of the same, if they exist.

2. After consulting the National Commission of Medications, the General Director of Pharmacy may decide to omit the informational prospect of some therapeutic indications whose disclosure is susceptible of bringing serious inconvenience to the patient.

SECTION III

Publicity

Article 38
(Definition)

For the purposes of the present diploma, any form of communication allusive to medications, with the purpose of promoting their acquisition or consumption, is considered publicity of the same.

Article 39
(General principles)

1. Publicity of medications in the mass media institutions is prohibited.

2. Publicity of medications who's AIM has not been granted is prohibited.

3. Publicity cannot differ from the information included in the summary of the medication's characteristics, such as it has been authorized.

4. Publicity must encourage the rational usage of medications, is an objective manner, and without exaggerating their properties.

5. Publicity must be conceived in such a manner that the advertisement appears clearly expressed, indicating that it's about a medication.

6. Medications obligatorily sold through medical prescription can be announced only in technical publications or audiovisual informational supports exclusively designed to physicians and other health professionals.

Article 40
(Publicity addressed to the public)

Publicity addressed to the public must contain the following minimal indications:

a) The medication's name;

b) Therapeutic indications and special precautions;

c) Information indispensable to the adequate usage of the medication;

d) Advise to the user to carefully read the informational prospect and, in case of doubt, to consult the physician when symptoms persist.

Article 41
(Prohibited publicity)

1. Publicity addressed to the public cannot contain elements that:

a) Lead to the conclusion that medical consultation or a surgical intervention is superfluous, and particularly suggesting a diagnosis or preconizing the treatment by correspondence;

b) Suggest that the medication's effect is guaranteed;

c) Suggest that the patient's health can be affected in case he doesn't use the medication;

d) Are addressed exclusively or mainly to minors;

e) Mention a recommendation made by scientists or health professionals;

f) Lead to confusion between the medication and a food product or cosmetics;

g) Suggest that the safety or efficacy of the medication is due to the fact that it is a natural product.

2. In the publicity mentioned in the previous number, are prohibited the therapeutic indications that may lead to self-medication, namely in the following illnesses:

a) Tuberculosis;

b) Sexually transmitted diseases;

c) Other serious infectious diseases;

d) Cancer;

e) Chronic insomnias;

f) Diabetes and other metabolism related illnesses.

3. Any comparative form of publicity is prohibited.

4. Publicity addressed to the public, of medications that have narcotics or psychotropic substances, is prohibited.

5. Free distribution of medications to the public, with promotional purposes, is prohibited.

Article 42
(Publicizing Documentation)

1. Documentation that is transmitted as promotion addressed to technicians qualified to prescribe or provide medications must include, at least, the following indications:

a) Summary of the medication's characteristics;

b) Indication of obligatory medical prescription, if that is the case.

2. The information contained in the information mentioned in the previous number must be exact, actual, verifiable and sufficiently complete to allow that the receiver has a correct idea of the therapeutic value of the medication.

3. The citations and illustrative material extracted from medical publications or scientific works, destined to be used in the documentation provided for on point 1, must be properly reproduced with the indication of the respective source.

Article 43
(Incentives)

1. To the person responsible for the promotions of medications it is prohibited to give or promise, directly or indirectly, offers, pecuniary or specie benefits, with exception of an object of insignificant intrinsic value.

2. It is prohibited to the prescribers and providers of medications to ask or accept any of the incentives provided for in the previous number.

3. The previous numbers' provisions are applicable without loss for what has been legally established in regards to mark-ups, prices and discounts.

Article 44
(Free samples)

1. Free samples destined to the promotion of medications may only be given to persons qualified to prescribe, under the following conditions:

a) To object of a request made by the receiver;

b) To be identical to the smallest commercialized presentation;

c) To contain the reference «free sample» and «Sale prohibited to the public» or other similar references;

d) To be accompanied by a copy of the summary of the medication's characteristics.

2. Samples of medications that contain narcotics or psychotropic substances cannot be given.

Article 45
(Civil responsibility)

1. The announcers, publicity agencies and other entities that exercise publicity activities, as well as the holders of publicity supports utilized, or the respective concessionaires, respond civilly and jointly, under the general terms, for losses caused to third persons, in result of the dissemination of illegal publicity messages.

2. The announcers will excuse themselves from the responsibility provided for in the previous number, in case they prove that they did not previously know about the disseminated message.

CHAPTER VI
Inspection

Article 46
(Competence)

The verification of the observance of the norms included in this diploma belongs to the General Inspection of Health.

Article 47
(Duty of information)

The entities authorized to practice the activities with the scope of this diploma are obligated to give all the information solicited by the General Inspection of Health.

Article 48
(Inspection)

1. The enterprise, establishment or place where there are medications, including narcotics or psychotropic substances, can be inspected at any time, and the exhibition of documents or records regarding the same may me solicited.

2. Before the inspection, the officer will identify himself through his proper card or credential issued by the General Inspection of Health, where his power to inspect is mentioned.

3. If the inspected entities refuse to exhibit the documents or records, and impede the inspection to the place, the police authorities will be asked to collaborate in order to accomplish the diligence.

4. A written report of each inspection will be elaborated, which will be filed in the General Inspection of Health, if it is not incorporated in judicial proceeding.

Article 49
(Obstacles to the inspection)

He who refuses to give elucidations or impedes or tries to stop another person from giving elucidations, or by any other means hinders the good exercise of the inspection, commits the crime provided for in articles 186 and 188 of the Penal Code, depending on the cases, without loss for the disciplinary proceedings that may take place in case it's a public officer.

Article 50
(Medications' quality control)

1. The analysis necessary for the quality control will be done in laboratory of medications' quality control.

2. For the purposes provided for in the previous number, the General Inspection of Health may collect samples of the medications already prepared or in any phase of their production, as well as the respective raw materials and conditioning materials.

3. This article's provision is extensive to the medicinal substances, cosmetics, and hygiene and/or prophylaxis products, and other products the Inspection deems convenient to inspect.

Article 51
(Apprehension of non authorized medications)

1. The medications put for sale without the necessary authorization will be apprehended by the General Inspection of Health.

2. The apprehended medications that are considered harmful to health will be destroyed, and the others will be distributed by the health care establishments.

Article 52
(Inspection of medications in transit)

The inspection must be exercised whenever it is necessary, even in regards to the medications in transit.

CHAPTER VII
Infractions

Article 53
(Production or commercialization without authorization)

1. The production and commercialization of medications, without authorization, or with suspended authorization is punishable with a 50.000$00 – 250.000$00 fine.

2. The production of medications without having a technical direction, according to Article 34 of this diploma, is punishable with the same fine as the previous number.

3. In the infractions provided for in the previous numbers, negligence and attempt are punished.

Article 54
(Sale of medications in bad state of conservation)

The offer to the public, of medications in bad state of conservation or whose validity has expired, or for any reason, must not be provided, is punishable with a 50.000$00 – 250.000$00 fine , without loss for the criminal responsibility that may apply to the case, according to the law.

Article 55
(Packages not labeled)

The offer of medications or medicinal substances in packages that are conveniently labeled is punishable with a 5.000$00 – 10.000$00 fine.

Article 56
(Offer of abortive products, toxics and other medications without prescription)

1. The offer of abortive substances, narcotics or toxics without medical prescription is punishable with a 50.000$00 – 150.000$00 fine.

2. The provision of medications and medicinal substances without prescription, when it's obligatory and outside of the cases provided for in the previous number, is punishable with a 30.000$00 – 100.000$00 fine.

3. The fine of paragraph 1 is applicable to the provision of medications and medicinal substances that are in disagreement with the prescription, as well as to the acceptance of the prescription in exchange of money or another product.

Article 57
(Sale of medications in non authorized establishments)

The provision of medications or medicinal substances in non authorized establishments is punishable with a 30.000$00 – 100.000$00 fine, and the established may be closed in case of reincidence.

Article 58
(Falsification of medications)

The falsification of medications or medicinal substances, the sale, acquisition, transport or warehousing for commerce of the mentioned medications or substances, are punishable with a 50.000$00 – 100.000$00 fine,

without loss for the criminal responsibility applicable to the case, according to the law.

Article 59
(Publicity)

The infraction to the provisions of articles 39 and 44 is punishable with a 2.000$00 – 50.000$00 fine, and may be applied as sanction accessory to suspension, until two years, of the medication's publicity.

Article 60
(Reincidence)

1. When there is reincidence, the minimum and maximum limits will be doubled.

2. Reincidence happens when an entity is punished for infraction provided for in this diploma, commits another infraction of the same nature, before a year has passed.

Article 61
(Application of the fines)

It belongs to the General Inspector of Health to apply the fines provided for in this diploma.

Article 62
(Fines' destination)

The product of the fines applied for the infractions sanctioned in this diploma constitutes public revenue.

CHAPTER VIII
Final provisions

Article 63
(Pharmaceutical vigilance)

1. The AIM holders, physicians, technical directors of pharmacies and other health technician must communicate to the DGF the adverse reactions they know about, resulting from the utilization of medications.

2. While a national pharmaceutical vigilance system is not created, DGF should study this information and propose the measures it deems convenient for the defense of public health.

Article 64
(Costs)

The costs of acts related to the proceedings provided for in this diploma and lab exams constitute the petitioners' charges, and the list is fixed by decree of the Government members in charge of Health and Finances.

Article 65
(Notifications)

The notifications to the petitioner, mentioned in this diploma, must be done in registered letter.

Article 66
(Revocation)

Article 50, 53, 93 to 105, and 164 of Decree n. 229/70, of May 15, 1971, and Article 1 to 7 of the Legislative Diploma n. 1419, of October 31, 1959 are revoked.

Article 67
(Vacatio legis)

1. This diploma will be applicable only to petitions of introduction in the market of new medications, after six months from its publication.

2. All the medications that are in the market and are included on the National List of Medications are subject to this diploma's provisions, and their approval and registration must be requested within the deadlines that will be fixed by dispatch of the Government member in charge of Health.

Seen and approved in the Cabinet.

Carlos Veiga – Rui de Figueiredo Soares.
Promulgated on January 28, 1993
Publish.
The President of the Republic, ANTÓNIO MANUEL MASCARENHAS GOMES MONTEIRO
Ratified on February 2, 1993
The prime Minister, *Carlos Veiga.*