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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

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

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)

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 gen2082 Ta(e5.1(pr)3.2 Ta(c)5.2(n),)-4.gf nlreadroArt0hTw(t0hTw(t0hTw(141Artw(ad)6.5ng)-5.2(mp

Article 22
(Requisites)

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

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
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Article 31

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.

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;

a) Name of the medication;

b) Quantity of active substances by pharmaceutical form;

c) Mode and canal of administration;

d) Validity;

e)

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)

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

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

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.

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.
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Publish.