LAW N°12/99 RELATING TO THE PHARMACEUTICAL ART

Title I. GENERALITIES

Article: 1
According to the terms of this Law, Pharmaceutical Art shall mean any act aimed at preparing, manufacturing, quality controlling, conditioning, preserving, and dispensing, even without charge, of drugs or other Pharmaceutical products.

The Pharmaceutical Art shall be practiced according to the Law and National policy as shall be determined by the Government on the proposal of the Minister responsible for Health.

However, this Law shall not affect acts performed by traditional practitioners within the framework of traditional medicine practice, which is governed by a specific law.

Article: 2
For the purpose of this Law, drug shall mean, any substance, preparation or composition presented as having preventive or curative properties towards human or animal diseases as well any products means to be given to man or animal with the aim of establishing a medical diagnosis, restoring correcting or modifying organic or psychic functions.

As for pharmaceutical product, it shall mean namely: 1. Drugs intended for human and veterinary medicine use;
2. Narcotics;
3. Sterile and non sterile medico-surgical material, dressing material and all the items presented as being in accordance with pharmacopoeias recognized in Rwanda;
4. Products and reagents conditioned for public sale and which, without being referred paragraph 1, are however intended for medical or pregnancy diagnosis;
5. Insecticides and acaricides intended for being applied to man or animal;
6. Products intended for maintenance or application of eye contact lenses.

For the purpose of this Law, magistral preparation shall mean any drug extemporaneously prepared in pharmacy on a duly authorized practioner's prescription and intended for a particular patient.

For the purpose of this Law, medicinal preparation means any drug prepared in pharmacy according to indications of pharmacopoeia or of the national form and dispensed to the patients of that pharmacy.

Article: 3
Blood and derived products are subject of a particular legislation

Article: 4
Preparation, manufacturing quality control, conditioning, preserving, export or distribution of dietetic, cosmetic and hygienic products as well as non-medicinal control products shall not be governed by this Law.

Article: 5
Drugs should be in accordance with the Rwandan pharmacopoeia as defined in Art of this Law. While waiting until the Rwandan pharmacopoeia is put in place, references made to another pharmacopoeia which will be designated by an order issued by the responsible for Health.

Article: 6
Unless derogation provided in this Law, the Minister responsible for health authorises a person to practice the Pharmaceutical Art:
1. If he/she is a holder of a duly acceptable university degree in pharmacy or of a recognized equivalent degree;
2. If he/she is registered on the roll of the Association of Pharmacists governing profession;
3. If he/she has a certificate of good conduct issued by the Association;
4. If he/she is of Rwandan nationality or, for a foreigner, if he/she has special authorization given by the Minister of Health after consultating the Association of Pharmacists.

Article: 7
The Pharmaceutical Art, in all its forms should be practiced in a pharmaceutical establishment, with complete freedom of action and independence in the interest of public heath and patient.

A pharmaceutical deontological code enacted by the Association of Pharmacists shall determine the conditions and modes of enjoyment of that freedom.

Title II. PHARMACEUTICAL ESTABLISHMENTS

Chapter 1. COMMON PROVISIONS

Article: 8
The Pharmaceutical Art shall be practiced individually or in association in the following pharmaceutical establishments:

- Retailing pharmacies;
- Establishments of wholesale, distribution and import of drugs and other pharmaceutics' products or pharmacies dealing with wholesale;
- Establishments of pharmaceutical production;
- Laboratories of quality control of pharmaceutical products.

Article: 9
Each establishment shall be run at least by a head pharmacists be it an agent or the own Establishment working full time for the Establishment. This one is personally responsible all

activities in the establishment to be in conformity with the provisions of this Law and all related texts.

No pharmacist can be in charge of more than pharmaceutical establishment.

Article: 10

The head pharmacist, in case of absence, shall find himself/herself another pharmacist authorized by the Minister responsible for Health to replace him/her.

In case he/she cannot find a substitute, he/she shall inform the regional authority responsible for pharmaceutical services.

Article: 11

A national commission for pharmaceutical establishment implementation is established.

An order issued by the Minister responsible for Health shall determine its composition and modes of functioning and the specific norms for setting up pharmaceutical establishments on national territory.

Article: 12

The opening and exploitation of pharmaceutical establishments on the national territory shall be subordinate to prior authorization of the Minister responsible for Health.

An order issued by the Minister responsible for Health shall determine the document accompanying the application for authorization.

The application of the authorization shall be sent, in a registered envelope, to the Minister responsible for Health, by the owner or by the person duly authorized to act on behalf of the establishment.

It shall be accompanied by the payment of a fee whose amount will be determined order issued by the Minister responsible for Health.

Article: 13

Authorization shall be granted by the Minister responsible for Health in consultation the national commission for pharmaceutical establishment implantation.

The authorization shall be personal. It should be granted or refused within a period of four months from the date of receipt for the application. The refusal shall be justified.

The authorization shall not exempt from possible authorizations required by other or regulatory provisions.

Article: 14

Authorization to open and exploit a pharmaceutical establishment, shall be granted indefinite period of time.

However, for the sake of the public health, the Minister responsible for Health can, inspector pharmacist's advice, at any time give an order to close for a maximum period of three months a pharmaceutical establishment, if the requirements provided for in this law are no fulfilled, or in case of incompetence of the head pharmacist.

The definitive canceling of authorization to exploit a pharmaceutical establishment is

subordinate to the joint decision of the council of the Association of Pharmacists and the Inspector Pharmacist.

Notification for temporary or definitive canceling shall be sent by mail in a registered envelope. Ministers responsible for Finance, and Commerce as well as the Court Clerk Accountant from where the register has been delivered shall be kept informed.

Article: 15
Decisions taken by the Minister in charge of Health concerning the temporary or definitive closing of a pharmaceutical establishment shall be liable to appeal before competent administrative jurisdictions

Article: 16
Any rectification of one of the constituent elements of the application for authorization shall be subjected to a prior statement issued by the Minister responsible for Health. Silence of the administration at the end of for four months equals authorization to rectify

Article: 17
Cession of activities of a pharmaceutical establishment shall be notified to the Minister responsible for Health and to the Clerk Accountant of the place where their establishment is exploiting within the following 30 days at the latest. The public will be informed by means of notice, legibly written, in at least one of the official languages, and visibly sticked up for a period of at least three months and under the responsibility and at the owner's possible expenses, at the main entrance of the exploitation site.

In default of public display, and in case the premises would be assigned to function which prevents the public from having free access to them, the notice will be published in at least two monthly newspapers published in Rwanda.

Article: 18
Technical conditions of running pharmaceutical establishments, technical conditions of hygiene and healthiness which should be fulfilled by any of the establishments above-mentioned, .as well as requirements of medical and professional nature which should be followed by people destined to work there, shall be determined by an order issued by the Minister responsible for health.

Article: 19
The Minister responsible for Health, can, for the sake of public health, impose on pharmaceutical establishments and all the persons he/she has authorized to deliver pharmaceutical products, the obligation to have a list of instruments, medico-surgical material and diagnostic products as well as a minimum quantity of drugs.

Chapter 2. SPECIFIC PROVISIONS

Section 1. RETAILING PHARMACIES

Article: 20
Retailing pharmacy means the establishment which mainly deals with dispense preparing, preserving and controlling the quality of drugs and other pharmaceutical product

Article: 21
With the exception of Public Health establishments or those linked to the state heal scheme and subsidiary to Article 6 of this Law, only a pharmacist shall be allowed to own a retailing pharmacy.

Without prejudice to the clauses in the preceding paragraph of this article and for major reasons of public health, the Minister responsible for Health for may after, consultation the Council of the Association of Pharmacists, authorize mutualistic associations and other non profit making Associations to open and exploit retailing pharmacies.

Article: 22
The retailing pharmacy should be accessible to the public in at least one of its components and display in legible characters the sign and the name of the pharmacist owning it.

Article: 23
Without prejudice to the clauses of Article 18 of the present Law, the Minister of H shall determine the minimum working hours the Head pharmacist must spend into Establishment.

Article: 24
In case it is impossible for him/her to fulfill the obligation stated in Article 23, pharmacist shall find himself/herself another one to replace him/her in accordance with Article of this Law.

No pharmacy should remain open in the absence of the Head pharmacist or his/her substitute.

Article: 25
In case the pharmacist's period of absence extends or must extend beyond six months, pharmacy should be taken over by someone else. In case of take, over, the successor pharmacist should be authorized by the Minister responsible for Health.

Article: 26
A decree issued by the Minister responsible for health shall determine the list of product other than those referred to in Article 2 paragraph 2 of this Law, which are supposed to be delivered in pharmacy.

Article: 27

Pharmacists practicing in the private sector for the benefit of third parties shall be conformity with the deontological code, entitled to honoraria or services they have provided.

Those honoraria should only cover the professional responsibility, handling, emergent services and specific obligations. They should also include any other honorarium explicitly define and recognized by law and regulations in force.

Section 2. WHOLESALE PHARMACEUTICAL ESTABLISHMENTS

Article: 28
Wholesale establishment means any establishment whose aim activity is storage, distribution and wholesale as well as import of pharmaceutical products whose list shall be determined by an order issued by the Ministry responsible for Health.

Article: 29
An legal entity or individual can acquire authorization to open and exploit a wholesale pharmaceutical establishment, provided that the technical responsibility is confided to a pharmacist.

Article: 30
Any import of drugs and other pharmaceutical products shall require a prior visa issued by the Minister responsible for Health.

Any effective entry of drugs and other pharmaceutical products on the national territory shall be subject to the presentation of any import license issued by the Minister responsible for Health after he/she has seen certificates of quality control of pharmaceutical products issued by the manufacturer.

Those requirements shall also apply to the pharmacists who import directly for their customer's needs as well as to the non governmental organizations and other organisms unless there exist specific conventions signed with the Rwandan State.

Article: 31
The holder of the authorization to open and exploit an establishment of wholesale, distribution and import of drugs and other pharmaceutical products should make necessary arrangements for the head pharmacist to be able to take on his/her mission. If the case arises, the latter can be assisted by other pharmacists.

Section 3. PHARMACEUTICAL PRODUCTION ESTABLISHMENTS

Article: 32
Pharmaceutical production establishments means any establishment in which are carried out on industrial scale, activities of manufacturing, analysis of drugs and other pharmaceutical products and control of their conformity to the standards required by laws and regulations in the country as well as their conditioning with the aim of marketing them on the national international markets.

The pharmaceutical production establishment can import raw materials, technical scientific material and appliances. The procedure provided for in Article 30 of this Law remains applicable.

Article: 33
Any legal entity or individual can have authorization to open and exploit a pharmaceutical production establishment, provided that the technical responsibility is confided to a pharmacist.

Article: 34
The head pharmacists shall record in a register, detailed phases of manufacturing and control analysis as well as their results. He/she will sign the conclusions drawn from them.

The register should be kept up to date. It shall be at the inspector pharmacist's disposal. It should be kept for at least ten years from the date of its closure

Article: 35
Authorization to manufacture drugs and other pharmaceutical products should indicate pharmaceutical form which it is valid and where they are manufactured.

Article: 36
Any pharmaceutical production establishment is required to see to it that the premises where manufacturing operations are carried out, the staff and factory scientific equipment be conformity with regulations of a good manufacturing practice's as recommended by the World Health Organization.

Article: 37
For the duration validity for the drug or other pharmaceutical products and for the following years, the head pharmacists shall put at the Pharmacy Inspectorate's disposal a sample of products whose conformity to the official standards has been certified. The sample should be sufficient quantity so as to allow carrying out required analysis.

Article: 38
The holder of an authorization to open and exploit a pharmaceutical production establishment should take measures for the head pharmacists to fulfill his/her mission and, if the case arises, to have him/her get helped by other pharmacists.

Section 4. LABORATORIES OF QUALITY CONTROL OF DRUGS AND OTHER PHARMACEUTICAL PRODUCTS

Article: 39

Laboratory of quality control means any establishment dealing with quality analysis drugs and other pharmaceutical products, and with control of their conformity to the official standards.

The results of analysis shall be recorded in a register reserved to that end. The register be kept for at least ten years from the closing date.

Article: 40

Laboratory of quality control means any establishment dealing with quality analysis drugs and other pharmaceutical products, and with control of their conformity to the official standards.

The results of analysis shall be recorded in a register reserved to that end. The register be kept for at least ten years from the closing date. Article 40: Authorization issued by the Minister responsible for Health shall specify the dully authorized types of analysis. Any rectification of types of analysis shall be subject to prior authorization issued by the Minister responsible for Health.

Title III. DRUGS AND OTHER PHARMACEUTICAL PRODUCTS

Chapter 1. GENERIC DRUGS AND PHARMACEUTICAL SPECIALITIES

Section 1. RECORDING OF GENERIC DRUGS AND PHARMACEUTICAL SPECIALITIES

Article: 41

Generic drugs means any drug, non protected by a patent, industrially prepared, a marketed unded the common international denomination of the active principle followed or not by the manufacturer's name.

Pharmaceutical speciality means any drug industrially prepared, protected or not by a patent, presented unded a specific conditioning and characterized by a special denomination.

Article: 42
A National Commission meant for drugs registration is established. An order issued by the Minister responsible for health shall determine its members and functioning.

Article: 43
Any generic drug and any pharmaceutical speciality put on the local market shall submitted to prior recording by the Minister responsible for Health. Application for registration shall be submitted for consultation to the Commission of Drug Registration whose composition and functioning shall be determined by an order issued by the Minister responsible for Health

Application for registration shall be sent to the Minister responsible for Health. It shall be accompanied by the payment of a fee whose amount shall be determined by an order issued Prime Minister.

Article: 44
Recording will only be granted to generic drugs and pharmaceutical specialties for which the manufacturer can justify among other things therapeutic interest, their innocuousness in normal conditions of use and of their intrinsic quality.

That recording shall be issued for period of five years. However, within the framework of the public invitation to tenders, the drugs which has been accepted, if it is not recorded, shall be automatically recorded for a period limited to the duration of the deal set up in the invitation to tenders.

Modes of recording will be determined by a Presidential order.

Any rectification of one of the technical constituent elements of the recording file should be subject to a new application to the Minister responsible for health.

Article: 45
The list of recorded generic drugs and pharmaceutical specialties shall be published each year in the Official Gazette of the Republic of Rwanda by the Minister responsible for Heal

Article: 46
Recording of a generic drug or of a pharmaceutical speciality shall leave full responsibility of the manufacturer towards third parties

Article: 47
When there are reasons for considering that effects of a drug could present an immediate danger to public health, the Minister responsible for Health can in consultation with the recording commission and on basis of a justified decision, postpone the delivery of that drug for a period of six months.

Withdrawal of the drug can be pronounced by the Minister responsible for Health after the manufacturer or his/her representative has been invited to give all explanation.

The manufacturer or his/her representative should take, in case of withdrawal or suspension, action with the aim of stopping delivering the drug in question to the public.

Article: 48
Magistral and medicinal preparations made by the pharmacist and delivered by himself / herself retail and without advertising shall not need recording.

Section 2. DRUG PRICE SCHEDULING

Article: 49
Modes of drug price scheduling shall be determined by an order issued by the Minister responsible for Health, in consultation with the Ministers responsible for Commerce and Finance.

Article: 50
No drug can be sold beyond the official price in the country

Article: 51
The tariff of generic drugs and pharmaceutical specialities shall be determined after having been recorded by the Minister responsible for Health.

As for the Magistral and medicinal preparation, prices shall be determined in conformity with provisions in Article 27 of this Law.

Article: 52
Pharmacy and Commerce Inspectorate services shall be responsible for controlling an enforcing the going tariff legislation in pharmaceutical establishments.

Section 3. DELIVERY OF DRUGS IN PHARMACY

Article: 53
The Minister responsible for Health shall determine drugs whose dispensing shall submitted to the presentation of a prescription of a duly authorized prescriber and modes of their dispensing.

Article: 54

Any prescription should be written in duplicate one for the Pharmacist and an other for the patient and contain the following inscriptions legibly written: 1. Name and full address of the author;
2. Registration number at the professional Association of the prescriber;
3. Date of the prescription;
4. Names, age, weight and sex of the patient;
5. Names of the prescribed products, their form, their administration and their dosage;
6. Signature of the prescriber.

Unless there is a specific note from the prescriber, the validity period of a prescription shall be limited to one month.

Article: 55

If in a prescription, dosages are not respected, the pharmacist will dispense the drugs after having consulted the prescriber.

If it is impossible for the pharmacist to consult the prescriber, or while he/she is waiting for the decisions to be made by this one, the prescription will be dispensed within the limit recommended dosages in the national form.

In this case the pharmacist shall explain to the patient the reasons for changing the dosage in the prescription and the reference to the new prescriber or any other physician equally qualified.

Article: 56

In case of incompatibility between two or among several prescribed drugs, the pharmacist will carry out dispension of the products only after having explained to the prescriber incompatibility in question shall consist of and proposed a rectification of the treatment accordingly.

Article: 57

The pharmacist shall be authorized to substitute a prescriber drug for another drug having the same active principle, if the substituted drug represents a lower price for the patient’s treatment and after the latter or his doctor has given prior agreement.

Article: 58

Any pharmacist should keep a prescription register in which he/she shall transcribe all drugs which are required to be registered as well as all the Magistral preparations carried his/her pharmacy.

An order issued by the Minister responsible for Health shall determine the information which should appear on the prescription register.

The prescription registers will be kept for ten years starting from the date of their closure.

Article: 59

Every pharmacy is required to mark any used prescription with the date, quantities delivered and the stamp.

Article: 60

Delivery of medical samples shall be authorized only in case of emergency and free of

charge.

Chapter 2. DANGEROUS, TOXIC PRODUCTS AND NARCOTICS

Section 1. DANGEROUS AND TOXIC PRODUCTS

Article: 61
Any pharmaceutical establishment can hold dangerous or toxic substances. They will keep aside, in a locked place, reserved for keeping such substance. They must be kept away from any other product.

An order issued by the Minister responsible for Health shall determine the list of dangerous or toxic products.

Drugs containing such substances should be made non accessible to the public.

Article: 62
Dangerous and toxic substances in kind will be kept in solid, watertight and properly closed containers bearing very visibly their usual denomination, as well as a special red-colored label marked A POISON printed in black characters and skull and crossbones.

Article: 63
Any drug containing one or dangerous or toxic substances cannot be dispensed with a duly authorized prescriber's prescription.

Article: 64
Any delivery of dangerous or toxic product will be written in a register whose pages be first numbered.

Inscriptions will be made soon after the sale. They will mention the date of sale; the buyer's identity as well as the uses they are intended for

Section 2. NARCOTICS

Article: 65
Narcotic means for the purpose of this act any natural or synthetic substance, preparation or composition intended for therapeutic or scientific use whose prolonged use provokes habituation and addiction likely to lead to drug addiction. An order issued by the Minister responsible for Health shall determine the list of narcotics.

Article: 66
A drug containing a narcotic will be delivered only on presentation of a prescription dated and signed by a duly authorized practitioner.

That prescription will be written in full, without any blank space or alteration and will mention the patient's full identity, the name and the quantity of the prescribed drug as well as the dosage in full.

The prescription cannot be renewed and can concern only a maximum of a week’s treatment.

It will be transcribed and underlined in red, without any alteration or correction on the prescription register.

Article: 67
On written, dated and signed request, the pharmacist shall be entitled to deliver narcotics to the directors of scientific laboratories on authorization of the Minister responsible for Health.

Any prescription or order for narcotic products has only 5 days of validity duration.

Article: 68
All those entire have narcotics in their possession should record in a special register whose will have previously been numbered and signed by the Minister responsible for Health or representative, the quantities they have for each substance.

The incoming quantities recorded in the register without any blank space or alteration, on a distinct page for each product.

Justification of outgoing quantities will be made by producing prescriptions and for fulfilled orders, classified in chronological order.

The special register, bills and written requests and any other written evidence relating to the narcotics should be kept for at least a period of ten years at the Pharmacy Inspectorate an judicial authorities' disposal.

Article: 69
All those who have narcotics in their possession should keep them in a locked reserved for keeping such substances.

Article: 70
Application for narcotic import shall be subject to prior authorization issued by the Minister

responsible for Health or his/her representative.

The importer should specify qualitatively and quantitatively the narcotics which are imported.

The application will not be examined unless he/she will have made known one year before import the estimate of the kind of products he/she wishes to import.

Article: 71
If the narcotic import concerns a consignment to be held in bond, in order to be then transferred abroad, the outgoing of those narcotics from the bonded warehouse is subject to license.

Narcotic import, export and warehousing licenses which were of no avail should be returned to the Ministry responsible for Health, in a period not exceeding six months.

Chapter 3. OTHER PHARMACEUTICAL PRODUCTS

Article: 72
Specific provisions relating to approval, tariff scheduling and dispensing of pharmaceutical products other than drugs can be specified by an order issued by the Minister responsible for Health

Chapter 4. ADVERTISING OF DRUGS AND OTHER PHARMACEUTICAL PRODUCTS

Article: 73
Advertising or propaganda means all the methods used by manufacturers and distributors with the aim of making known their drugs and other pharmaceutical products or their establishments.

Advertising or propaganda of drugs and other pharmaceutical products and of production and distribution establishments shall only be authorized under the conditions as shall determine by an order issued by the Minister responsible for Health.

He can ban any advertising or propaganda action susceptible of bringing about public health risks.

Any advertising relating to a drug or any other pharmaceutical product which subject to a suspension measures shall be banned.

Article: 74
Any form of advertising which is capable of misleading the public or giving them biased or incomplete information about preventive, diagnostic or curative properties of drugs and of pharmaceutical products shall be prohibited.

Title IV. RWANDAN PHARMACOPOIEA AND THE NATIONAL FORM

Article: 75
Rwandan Pharmacopoeia means all the rules to follow for preparing, analysis, preserving and using drugs and other pharmaceutical products, as well as the related required norms. The content shall be determined by the Minister responsible for Health.

Article: 76
A national commission of Rwandan pharmacopoeia responsible for the ongoing updating of the latter shall be established.

The composition and the functioning rules of it shall be determined by an order issued by the Minister responsible for Health.

Article: 77
A national form shall be published by the Minister responsible for Health. It shall bring together synthetically scientific and technical information relating to drugs under their generic names.

It can be completed by further information that shall be of interest to health, within framework of their activity related to drugs.

Article: 78
Every pharmaceutical establishment is required to have a copy of an edition in force of Rwandan Pharmacopoeia and the National form.

Title V. INTERDICTIONS AND INCOMPATIBILITIES

Article: 79
Any public display or sale of drugs and other pharmaceutical products outside pharmacies shall be prohibited.

The use of the term "Pharmacy" shall be prohibited within framework of any commercial activity carried out outside a pharmaceutical establishment.

Article: 80
Selling and keeping in a point of sale drugs and other pharmaceutical products which are

soiled, contaminated, altered, expired, adulterated or whose origin is not indicated, shall be prohibited.

Article: 81
It is prohibited for any health professional from delivering, requesting or accepting directly or indirectly while supplying drugs and other pharmaceutical products, bonuses, benefits or of whatever nature it may be. Moreover any medico-pharmaceutical collusion is prohibited.

Article: 82
Practicing simultaneously the pharmaceutical art and one of the branches of the art medicine or any related professions shall be prohibited.

However, the physician practicing private capacity is required to have in his office a stock of emergency drugs whose list quantity shall be determined by an order issued by the Minister responsible for Health.

Article: 83
Using on humans drugs intended for veterinary use shall be prohibited.

It is prohibited to keep in the same place veterinary drugs and drugs meant for human beings treatment.

Title VI. PHARMACY INSPECTORATE

Article: 84
The Minister responsible for Health shall be responsible for inspecting any location on the national land where drugs and other pharmaceutical products are manufactured; conditioner stored, analyzed or delivered.

Inspectors delegated to this end to the Ministry responsible for Health should be holder of a diploma in pharmacy.

They shall keep to professional secrecy. They shall monitor the enforcement of this law and measures taken for its enforcement.

They are invested of prosecutions officer's authority for any disobedience to this Law.

A Ministerial order shall determine duties related to the inspector pharmacist’s function as well as the conditions of their execution.

Article: 85
The inspector pharmacist's functions shall be incompatible with that of owning or joint owning a pharmaceutical establishment or holding shares in it.

Inspector pharmacists shall also be prohibited from inspecting any establishment in which they have financial interests or blood relationships in direct collateral line to the 2nd degree with the owners, shareholders or head pharmacists.

Article: 86

The inspector pharmacist shall allow to enter any establishment or any place where he/she presumes that activities related to the pharmaceutical art are carried out.

No one can escape or oppose on any account to the accomplishment of the inspector pharmacist' mission.

The inspector pharmacist can, when necessary, take samples for analysis purposes.

Article: 87

The inspector pharmacists shall note, in reports deemed authentic, that there have been infractions of this Law and the decrees stating measures for its enforcement until there evidence that it's not the case.

There will be made as many copies as necessary, one of which shall be addressed to the offender within seven days at the latest from the day the infraction has been noted.

Article: 88

If there is strong presumption that drugs and other pharmaceutical products found are soiled, expired, counterfeited, adulterated or in non conformity with the provisions of this law or the decrees stating measures for its enforcement, the inspector pharmacists, in agreement with the interested persons, can if necessary proceed to immediately destroy those products or remove them with the aim of destroying them, without prejudice to possible legal proceedings.

If no consent of the interested person the drugs and other pharmaceutical products shall be and the seals put on them.

The inspectors shall have samples taken for analysis in an adequately equipped laboratory.

Depending on the results of the analysis, either the seals shall be removed or the s maintained before they are possibly destroyed.

Article: 89

In the interest of public health, the inspector pharmacist, with an ad hoc report whose copy is given to the offender, can proceed to confiscate drugs and other pharmaceutical products deemed to be in non conformity with the standards enacted by law.

He/she shall refer it to the Public Prosecutor within seven days from the day of the operation. Article 90: The Minister responsible for Health determines the mode and conditions of taking samples for analysis and of confiscation.

Title VII. PENAL PROVISIONS

Article: 91

Whoever engages in activities reserved to pharmacists without fulfilling the legal requirements will be punished by imprisonnement of more than two months and less than one year and a fine not exceeding fifty thousand Rwandan francs or with only one of those penalty

In both cases, the establishment is closed.

Article: 92
Whoever engages in import of pharmaceutical products without authorization will be punished by imprisonment not exceeding one year and a fine amount of one million Rwandan francs or with only one of those penalties.

Article: 93
He who will successfully or unsuccessfully attempt to escape or oppose on any account to the mission of the inspector pharmacists or that of other duly appointed persons will incur the penalties provided for in Article 91 of this Law.

Article: 94
He who engages in unauthorized accumulation of pharmaceutical activities will incur the penalties provided for in Article 92 of this Law.

Article: 95
Home trafficking, brokerage and displaying drugs and other pharmaceutical products markets or public places or in any other unauthorized place will be punished by imprisonment not exceeding one year or with a fine not less than one hundred thousand Rwandan francs and not exceeding five hundred thousand Rwandan francs or with only one of those penalties.

Article: 96
Selling and delivering adulterated or altered drugs and other pharmaceutical products will be punished by imprisonment of more than one month and not exceeding one year and a fine not less than five hundred thousands Rwandan francs and not exceeding one million or with only on those penalties.

Whoever sells or delivers expired drugs will incur a fine not less than one hundred thousand Rwandan francs and not exceeding five hundred thousands Rwandan francs,plus the possibility of closing down the establishment for a period of three months.

Title VIII. TRANSITIONAL AND FINAL PROVISIONS

Chapter 1. PHARMACEUTICAL POINTS OF SALE AND TRANSITIONAL PROVISIONS

Article: 100
Notwithstanding the legal provisions in Article 6 and 8 and for public health reasons, Ministry responsible for Health can authorized, in consultation with the national

commission implementation, the opening and exploitation of a pharmaceutical point of sale by an A1, A2, A3, nurse or by a pharmacist assistant, in a location which is not served by a pharmacy.

Article: 101
Pharmaceutical point of sales means any premise where the pharmaceutical active limited to the preservation and retail distribution of some drugs and other pharmaceutical products whose list shall be determined by an order issued by the Ministry responsible for Health.

Activities of a pharmaceutical point of the sale should be supervised and advised by the regional authority in charge of pharmaceutical services.

Article: 102
Application for the opening and exploitation shall be addressed in a registered envelope to the Ministry responsible for Health by one of the persons mentioned in Article 98 of this law.

An order issued by the Minister responsible for Health shall determine the documents information accompanying the application.

Article: 103
Authorization to open and exploit a pharmaceutical point of sale shall be granted only a temporary basis and for one point of sale for a period of 3 years.

If a pharmacy fulfilling the requirements provided for in this Law is set up in the served by the point of sale the authorization to exploit the point of sale in question shat withdrawn.

A delay of 2 years is granted for the definitive closing down of the mentioned point of or its transfer to another area without a pharmacy. That authorization is incompatible, except pharmaceutical points of sale open in the public or authorized health centers, with activities of other branches of the art of healing and related professions.

Authorization to open and exploit a private pharmaceutical point of sale is individual non transferable.

Article: 104
The person entitled to a pharmaceutical point of sale is responsible for the enforcement of the provisions of this Law relating to pharmaceutical establishments. He/she is subject to the control by the inspector pharmacists

Article: 105
Penal provisions provided in section VII of this Law are applicable in case of pharmaceutics points.

Article: 106
Until the Association of Pharmacists is put into place the mission assigned to it will temporarily be ensure by the Minister responsible for Health

Chapter 2. FINAL PROVISIONS

Article: 107
All the previous provisions governing the pharmaceutical art to date are abrogated.

Article: 108
This law comes into force after sixty days starting from the date of its publication in the Official Gazette of the Republic of Rwanda