LAW Nº 26842 – GENERAL HEALTH LAW

GENERAL LAW OF HEALTH

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PRELIMINARY TITLE

I. Health is an indispensable condition for human development and a fundamental means to achieve individual and collective well-being.

II. Health protection is of public interest. Therefore, it is the responsibility of the State to regulate, monitor and promote it.

III. Every person has the right to the protection of their health under the terms and conditions established by law. The right to health protection is inalienable.

The conceived child is a subject of law in the field of health.

IV. Public health is the primary responsibility of the State. Responsibility for individual health is shared by the individual, society and the State.

V. It is the responsibility of the State to monitor, prevent and address the problems of malnutrition and mental health of the population, those of environmental health, as well as the health problems of the disabled, the child, the adolescent, the mother and the elderly in situation of social abandonment.

SAW. The provision of health services is of public interest, regardless of the person or institution that provides them. It is the responsibility of the State to promote the conditions that guarantee adequate coverage of health benefits to the population, in socially acceptable terms of security, opportunity and quality.

The responsibility of the State in the provision of public health services is inalienable. The State intervenes in the provision of health care services in accordance with principles of equity.

VII. The State promotes the universal and progressive insurance of the population for the protection of contingencies that may affect their health and guarantees the free choice of pension systems, without prejudice to a system compulsorily imposed by the State so that no one is left unprotected.

VIII. State financing is preferably directed toward public health actions and to fully or partially subsidize medical care for low-income populations who do not enjoy coverage under another health care regime, public or private.

IX. The health standard is of public order and regulates health matters, as well as the protection of the environment for health and medical assistance for the recovery and rehabilitation of people's health.

No one can agree against it.

X. Every person within the national territory is subject to compliance with the health standard. No foreigner can invoke its territorial law in matters of health.

XI. In the event of a defect or deficiency in the health standard, the general principles of law apply.

XII. The exercise of the right to property, the inviolability of the home, free movement, freedom of work, business, commerce and industry as well as the exercise of the right of assembly are subject to the limitations established by law to protect the public health.

Reasons of conscience or belief cannot be invoked to exempt oneself from the provisions of the Health Authority when such exemption results in risks to the health of

third parties.

XIII. The use or usufruct of goods in hygienic and sanitary conditions that are not apparent for the purpose for which they are intended constitutes an abuse of the right, whatever the regime to which they are subject.

XIV. Health information is of public interest. Every person is obliged to provide the Health Authority with the information required by law. What the State has in its possession is in the public domain, with the exceptions established by law.

XV. The State promotes scientific and technological research in the field of health, as well as the education, training and training of human resources for health care.

XVI. The State promotes health education at all levels and modalities.

XVII. The promotion of traditional medicine is of interest and preferential attention of the State.

XVIII. The State promotes community participation in the management of public health services.

TITLE I

OF THE RIGHTS, DUTIES AND RESPONSIBILITIES CONCERNING THE INDIVIDUAL HEALTH

Article 1.- Every person has the right to free access to health benefits and to choose the pension system of their preference.

Article 2.- Every person has the right to demand that the goods intended for health care correspond to the characteristics and attributes indicated in their presentation and to all those that were accredited for their authorization.

Likewise, you have the right to demand that the services provided for your health care meet the standards; of quality accepted in institutional and professional procedures and practices.

Article 3.- Every person has the right to receive, in any health establishment, emergency medical-surgical care when they need it and as long as the state of serious risk to their life or health persists.

The regulation establishes the criteria for qualifying the emergency situation, the conditions for reimbursement of expenses and the responsibilities of the drivers of the establishments.

Article 4.- No person may be subjected to medical or surgical treatment without their prior consent or that of the person legally called upon to give it, if appropriate or if they are prevented from doing so. Emergency interventions are exempt from this requirement.

Refusal to receive medical or surgical treatment exempts the treating doctor and the health establishment from liability, if applicable.

In the event that the legal representatives of the absolutely incapable or the relatively incapable, referred to in the

numerals 1 to 3 of Article 44 of the Civil Code, deny their consent for the medical or surgical treatment of their dependents, the treating physician or the health establishment, where applicable, must notify the competent judicial authority to expedite the actions that may be taken to safeguard their life and health.

The regulation establishes the cases and formality requirements that must be observed for the consent to be considered validly issued.

Article 5.- Every person has the right to be duly and timely informed by the Health Authority about hygiene measures and practices, adequate diet, mental health, reproductive health, communicable diseases, chronic degenerative diseases, early diagnosis of diseases and other conducive actions. to the promotion of healthy lifestyles. You have the right to receive information about the risks caused by smoking, alcoholism, drug addiction, violence and accidents.

Likewise, you have the right to demand that the Health Authority provide you, without giving cause, information on health matters, in accordance with the provisions of this law.

Article 6.- Every person has the right to freely choose the contraceptive method of their preference, including natural ones, and to receive, prior to the prescription or application of any contraceptive method, adequate information about the available methods, their risks, contraindications. , precautions, warnings and physical, physiological or psychological effects that its use or application may cause.

For the application of any contraceptive method, the patient's prior consent is required. In the case of definitive methods, the declaration of consent must be in a written document.

Article 7.- Every person has the right to resort to treatment for their infertility, as well as to procreate through the use of assisted reproduction techniques, provided that the condition of genetic mother and surrogate mother falls on the same person. For the application of assisted reproduction techniques, the prior written consent of the biological parents is required.

The fertilization of human eggs for purposes other than procreation is prohibited, as is the cloning of human beings.

Article 8.- Every person has the right to receive organs or tissues of live human beings from corpses or animals to preserve their life or recover their health. You can also dispose of your organs and tissues free of charge for transplant, graft or transfusion purposes, as long as this does not cause serious damage to your health or compromise your life.

The disposal of organs and tissues of living human beings is subject to the express written consent of the donor. The representatives of the incapable,

included within the scope of Article 4 of this law, lack the legal capacity to grant it.

For the disposal of organs and tissues of corpses, what is declared in the National Identity Document will be followed, unless a subsequent declaration to the contrary made while alive by the deceased that is unquestionably recorded and the cases provided for in Article 110 of this law.

In the event of the death of a person, without the person having expressed during life his/her willingness to donate his/her organs or tissues, or his/her refusal to do so, it is up to his/her closest relatives to arrange it.

Article 9.- Any person who suffers from a physical, mental or sensory disability has the right to treatment and rehabilitation. The State gives preferential attention to children and adolescents.

People with severe disabilities, also affected by an illness, have preference in their health care.

Article 10.- Every person has the right to receive healthy and sufficient food to cover their biological needs. Feeding people is the primary responsibility of the family.

In nutrition and food assistance programs, the State provides preferential attention to children, pregnant and lactating mothers, adolescents and the elderly in situations of social abandonment.

Article 11.- Every person has the right to recovery, rehabilitation and promotion of their mental health. Alcoholism, drug dependence, psychiatric disorders and family violence are considered mental health problems. Mental health care is the primary responsibility of the family and the State.

Article 12.- The obligations referred to in Articles 10 and 11 of this law are enforceable by the State or by those who have a legitimate interest, to those responsible or family members, in accordance with the provisions of Articles 473 et seq. of the Third Book, Fourth Section, Title I, Chapter I, of "Food", of the Civil Code. In the case of children or adolescents, what is provided by the law on the matter will apply.

In cases where, due to the absence of family, the person is unprotected, the State must assume their protection.

Article 13.- Every person has the right to have their health status certified whenever they consider it appropriate.

No public authority may require people to certify their health status, health card, health card or similar document, as a condition for the exercise of professional, production, commercial or related activities.

The provisions of this provision do not exempt people from compliance with the provisions related to the vaccination card or certificate, in accordance with what is established by the health standard, nor from those related to the certification of their health status as a requirement. to obtain licenses for

drive vehicles, ships and aircraft, or handle weapons or explosives in accordance with the law of the matter.

Article 14.- Every person has the right to participate individually or in association in programs to promote and improve individual or collective health.

Article 15.- Every person, user of health services, has the right:

a) To respect their personality, dignity and privacy;

b) To demand the confidentiality of information related to the medical procedure and your medical history, with the exceptions established by law;

c) Not to be subjected, without their consent, to exploration, treatment or exhibition for educational purposes;

d) Not to be subject to experimentation for the application of medications or treatments without being duly informed about their experimental condition, the risks they run and without prior written consent or that of the person legally called to give it, if appropriate, or if it is prevented from doing so;

e) Not to be discriminated against due to any illness or disease that affects them;

f) To be provided with truthful, timely and complete information about the characteristics of the service, the economic conditions of the provision and other terms and conditions of the service;

g) To be given in understandable terms complete and continuous information about their process, including diagnosis, prognosis and treatment alternatives, as well as the risks, contraindications, precautions and warnings of the medications prescribed and administered;

h) To be informed of everything necessary to give informed consent prior to the application of any procedure or treatment, as well as to refuse it;

i) To be given the discharge report at the end of your stay at the health facility and, if requested, a copy of the epicrisis and your medical history.

Article 16.- Every person must ensure the improvement, conservation and recovery of their health and that of their dependents.

The personal duty to care for and preserve one's own health can only be demanded when such omission is likely to have a negative impact on public health or that of third parties.

Article 17.- No person may act or assist in practices that cause danger, impairment or damage to the health of third parties in the population.

Article 18.- Every person is responsible to third parties for non-compliance with sanitary and hygiene practices aimed at preventing the appearance and

spread of communicable diseases, as well as by acts or events that cause environmental contamination.

Article 19.- It is the obligation of every person to comply with the safety standards established by the relevant provisions and to participate and collaborate in the prevention and reduction of risks due to accidents.

Article 20.- It is the duty of every person to participate in the improvement of the health culture of their community.

Article 21.- Every person has the duty to participate and cooperate with public authorities in the prevention and solution of problems caused by disaster situations.

Title II

OF THE DUTIES, RESTRICTIONS AND RESPONSIBILITIES IN CONSIDERATION OF THE HEALTH OF THIRD PARTIES

CHAPTER I

OF THE EXERCISE OF MEDICAL PROFESSIONS AND RELATED ACTIVITIES TECHNIQUES AND AUXILIARIES IN THE FIELD OF HEALTH

Article 22.- To carry out professional activities related to medicine, dentistry, pharmacy or any other related to health care, it is required to have a professional title in cases where the law establishes it and to comply with the requirements of membership, specialization. , licensing and others provided by law.

Article 23.- The incompatibilities, limitations and prohibitions, as well as the sanctions regime applicable to the professionals referred to in this Chapter, are governed by the Codes of Ethics and statutory regulations of the corresponding Professional Associations.

Article 24.- The issuance of prescriptions, certificates and reports directly related to patient care, the execution of surgical interventions, the prescription or experimentation of drugs, medications or any product, substance or agent intended for the diagnosis, prevention or treatment of diseases. , are considered acts of the professional practice of medicine and are subject to the supervision of the corresponding Professional Associations.

Article 25.- All information related to the medical act that is performed is reserved.

The health professional, technician or assistant who provides or discloses, by any means, information related to the medical act in which he participates or of which he has knowledge, incurs civil or criminal liability, as the case may be, without prejudice to the sanctions that correspond in application of the respective Codes of Professional Ethics.

The following cases are exempt from the reservation of information related to the medical act:

a) When there is written consent from the patient;

b) When required by the competent judicial authority;

c) When it is used for academic or scientific research purposes, provided that the information obtained from the clinical history is recorded anonymously;

d) When it is provided to family members or close friends of the patient with the purpose of benefiting them, as long as the patient does not expressly prohibit it;

e) When it concerns diseases and damages that must be declared and notified, as long as it is provided to the Health Authority;

f) When it is provided to the insurance entity or financing administrator linked to the care provided to the patient, provided it is for the purposes of reimbursement, payment of benefits, supervision or audit; and,

g) When necessary to maintain continuity of medical care to the patient.

Information on the diagnosis of injuries or damages in the cases referred to in Article 30 of this law must be provided to the police authority or the Public Ministry upon request.

Article 26.- Only doctors can prescribe medications. Dental surgeons and midwives can only prescribe medications within the area of their profession.

When prescribing medications, they must state their International Nonproprietary Name (INN), the brand name if any, the pharmaceutical form, dosage, dosage and administration period. Likewise, they are obliged to inform the patient about the risks, contraindications, adverse reactions and interactions that its administration may cause and about the precautions that must be observed for its correct and safe use.

Article 27.- The treating doctor, as well as the surgeon-dentist and the obstetrician are obliged to inform the patient about the diagnosis, prognosis, treatment and management of their health problem, as well as the risks and consequences thereof.

To apply special treatments, perform risky tests or perform interventions that may affect the patient mentally or physically, the doctor is obliged to obtain written informed consent.

Article 28.- Experimental research with people must adhere to the special legislation on the matter and the ethical postulates contained in the Helsinki Declaration and successive declarations that update the aforementioned postulates.

Article 29.- The medical act must be supported by a truthful and sufficient clinical history that contains the practices and procedures applied to the patient to resolve the diagnosed health problem.

The minimum information that the medical history must contain is governed by the regulations of this law.

The doctor and the dental surgeon are obliged to provide a copy of the medical history to the patient if the patient or his representative requests it. The interested party assumes the cost of the order.

Article 30.- The doctor who provides medical care to a person injured by a knife, gunshot wound, traffic accident or due to another type of violence that constitutes a crime prosecutable ex officio or when there are indications of criminal abortion, is obliged to bring the matter to the attention of the competent authority.

Article 31.- It is the responsibility of the treating doctor, the medical examiner who performs the autopsy or the doctor designated by the health establishment in which the person's death occurs, to properly issue the corresponding death certificate.

Article 32.- Health professionals, technicians and assistants are obliged to inform the Health Authority of cases of diseases and damages requiring mandatory declaration and notification.

Article 33.- The chemist-pharmacist is responsible for dispensing and providing information and guidance to the user on the administration, use and dosage of the pharmaceutical product, its interaction with other medications, its adverse reactions and its storage conditions.

Likewise, it is authorized to offer the user alternative medications that are chemically and pharmacologically equivalent to that prescribed in the prescription, in the same pharmaceutical form and dosage.

Article 34.- Health professionals who detect serious adverse reactions to medications are obliged to report them to the national Health Authority, or to whomever it delegates, under responsibility.

Article 35.- Those who carry out professional, technical or auxiliary activities related to people's health will be limited to exercising them in the area that the legally issued title, certificate or authorization determines.

Article 36.- The professionals, technicians and assistants referred to in this Chapter are responsible for the damages and losses caused to the patient by the negligent, reckless and reckless exercise of their activities.

Chapter II

OF HEALTH FACILITIES AND MEDICAL SUPPORT SERVICES

Article 37.- Health establishments and medical support services, whatever their nature or management modality, must comply with the requirements established by the regulations and technical standards dictated by the National Health Authority in relation to physical plant, equipment. , healthcare personnel, sanitation systems and risk control related to physical, chemical, biological and ergonomic environmental agents and others that proceed based on their nature and complexity.

The Health Authority at the national level or to whomever it delegates, will periodically verify compliance with the provisions of this provision.

Article 38.- The health establishments and services referred to in this Chapter are subject to the periodic evaluation and control and audits provided by the National Health Authority.

The national Health Authority dictates the corresponding evaluation and control and audit standards.

Article 39.- Health establishments, without exception, are obliged to provide emergency medical-surgical care to those who need it and while the state of serious risk to their life or health persists, in the manner and conditions established by the regulations. .

Article 40.- Health establishments and medical support services have the duty to inform the patient and their family members about the characteristics of the service, the economic conditions of the provision and other terms and conditions of the service, as well as the essential aspects related to it. with the medical act.

No health establishment or medical support service may carry out actions that correspond to acts that have not been previously authorized by the patient or by the person legally called upon to do so, if applicable, or who is prevented from doing so, in accordance with the provisions of the regulations of this law.

Emergency care intended to address a situation that puts the life or health of the patient in imminent danger is excepted from the provisions of the preceding paragraph.

Article 41.- Every health establishment must, at the time of admission, state in writing the patient's willingness to donate, in the event of death, his or her organs and tissues for the purposes of transplantation, grafting, teaching or research, or, as appropriate. case, the refusal to do so. Emergency admission is excepted from the provisions of this provision.

Article 42.- Any medical act carried out in a health establishment or medical support service is susceptible to internal and external audits in which the various procedures to which the patient is subjected can be verified, whether these are to prevent, diagnose, , cure, rehabilitate or carry out research actions.

Article 43.- Article 25 and the first and second paragraphs of Article 29 of this law are applicable to health establishments.

In the cases provided for in Article 30 of this law, the treating doctor will inform the Director of the establishment, who must inform the competent authority of the corresponding fact.

Article 44.- Upon discharge of the patient, the person in charge of the health facility is obliged to deliver to the patient or his representative the discharge report that contains the admission diagnosis, the procedures carried out, the discharge diagnosis, prognosis and recommendations of the condition that warranted internment.

Likewise, when the patient or his representative requests it, he must provide a copy of the epicrisis and the medical history, in which case the cost will be assumed by the interested party.

Article 45.- The ablation of organs or tissues for transplant or graft purposes can only be carried out in duly authorized health establishments or in medico-legal institutions, complying, in each case, with the procedures established by law. Organ transplants or tissue grafts can only be carried out in health establishments that have specialized services duly accredited for this purpose.

The ablation of organs and tissues as well as their transplant or graft are governed by this law, the law of the matter and its regulations. Health establishments may only have organs and tissues for transplant or graft purposes free of charge.

The health establishments that the national Health Authority authorizes may install and maintain, for therapeutic purposes, physical banks of organs and tissues.

Article 46.- The activities of obtaining, donation, conservation, transfusion and supply of human blood, its components and derivatives, as well as the operation of blood banks, hemotherapy centers and blood product plants, are governed by the law of the matter. and its regulations and are subject to supervision and control by the National Health Authority or whoever it delegates.

Article 47.- Health establishments that have patient confinement services are obliged to perform autopsy for clinical reasons to monitor the quality of the care they provide, as long as they have prior authorization from the patient or their family members. , in the absence of a declaration made during his lifetime, in accordance with the provisions of Article 13 of the Civil Code.

It is not appropriate to perform autopsies for clinical reasons when the circumstances of the patient's death imply the obligation to perform a legal autopsy.

Article 48.- The health establishment or medical support service is jointly and severally responsible for the damages and losses caused to the patient, derived from the reckless or negligent exercise of the activities of the professionals, technicians or assistants who work there with dependency relationship.

It is exclusively responsible for the damages and losses caused to the patient for not having arranged or provided the means that would have prevented them from occurring, provided that the provision of said means is required taking into account the nature of the service offered.

Chapter III

OF PHARMACEUTICAL AND GALENIC PRODUCTS, AND RESOURCES NATURAL THERAPEUTICS

Article 49.- The Health Authority at the national level is in charge of sanitary control of pharmaceutical and galenic products, as well as ensuring compliance with the provisions on the matter established in this law and the regulations.

Article 50.- All products included in this Chapter require Sanitary Registration for their manufacture, import, distribution or sale.
Any modification must also be recorded in said Registry.

Only the pharmaceutical formulas indicated in the following works, in their latest editions and supplements, may be registered or re-registered in the Health Registry of medicines:

- USP

- British Pharmacopoeia

- International Pharmacopoeia of the World Health Organization

- British National Form

- German Pharmacopoeia

- French Pharmacopoeia

- Belgian Pharmacopoeia

- European Pharmacopoeia

- USP-DI

- Helvetica Pharmacopoeia

- Japanese Pharmacopoeia

To obtain the Health Registry of medicines, under no conditions will the health authority require other documents, visas, prerequisites or conditionality of any kind, other than those indicated below, under responsibility:

to. Application in the form of a sworn declaration, entering the number corresponding to the Unified Registry of the applicant natural or legal person, and guaranteeing the quality, safety and effectiveness of the product.

b. Analysis protocol based on the methodological basis of one of the authorized pharmacopoeias.

c. Free marketing certificate and consumption certificate from the country of origin, issued by the competent authority. Alternatively, both certifications may appear in a single document.

d. Medium and immediate packaging labeling project in Spanish.

Products whose formulation is not yet included in the aforementioned works, which are authorized by the competent authorities of the country of origin, may also be registered. In this case, the requirements established in paragraphs a), c) and d) of this article will be required. With regard to the analysis protocol referred to in literal b), it must be based on

the methodologies applied in their country of origin, which will serve as a basis for subsequent quality control.

Registration in the Health Registry of medicines is automatic, with the sole presentation of the documents established in this provision, with the health authority having a maximum period of 7 business days to issue the document proving the registration number.

Article 51.- The National Health Authority approves the National Medicines Formulary, which contains the list of medicines that have a health registration in the country. This Form automatically incorporates the registered products.

The National Formulary will be prepared by a Commission of Experts, whose composition and functions will be determined by the corresponding regulations, and will specify the pharmaceutical form, dosage, indications, contraindications, adverse reactions, warnings and other specifications that guarantee efficacy and safety for the patient. use of medications.

The guidelines for the preparation and updating of the aforementioned Form are established in the regulations.

Article 52.- For the importation of pharmaceutical and galenic products, the Customs of the Republic, under responsibility, will proceed to dispatch them, requiring only a sworn declaration stating the following: a) the health registration number or, failing that, the date of submission of the corresponding application; and b) identification of the shipment by production lot and expiration date of the medication; without prejudice to the general documentation required for imports. Additionally, in the case of pharmaceutical products derived from human blood, an Analytical Certificate of Negativity for Human Immunodeficiency Viruses and Viral Hepatitis B and C will be required for each manufacturing batch.

The company name and unified registration of the importer or general distributor must be printed or labeled on each container sold to the consumer, along with the expiration date of the medication.

The National Health Authority may provisionally authorize, in duly qualified cases, the import and sale, without prior registration, of the corresponding products included in this chapter, for emergency medicinal uses.

Article 53.- For exclusive research purposes, the import, production and use of unregistered medications may be authorized, in accordance with the corresponding regulatory provisions.

Article 54.- The Health Registry is temporary and renewable every five years.

The national Health Authority may suspend or cancel the Registration of products that do not comply with the technical specifications that support their granting.

Likewise, the suspension or cancellation of the Health Registry will proceed when scientific information coming from the World Health Organization

determine that the product is unsafe or ineffective in its use in the terms in which its registration was authorized.

Article 55.- The manufacture, import, possession, distribution and transfer in any capacity of pharmaceutical products and others indicated in the regulations, contaminated, adulterated, falsified, altered and expired, is prohibited.

The aforementioned products must be immediately removed from the market and destroyed appropriately, under responsibility.

Article 56.- To carry out their activities, natural or legal persons who are dedicated to the manufacture or storage of pharmaceutical products or carry out part of the processes they comprise, must have adequate and sufficient premises, technical and control equipment as established. establishes the regulations. Likewise, they must adhere to the Good Manufacturing, Laboratory and Storage Practices recommended by the World Health Organization or those issued by the National Health Authority, and to the technical manufacturing standards as appropriate.

The Health Authority at the national level or to whomever it delegates, will periodically verify compliance with the provisions of this provision.

Article 57.- The person responsible for the quality of pharmaceutical products is the manufacturing company, if they are manufactured in the country. In the case of products manufactured abroad, the responsibility lies with the importer or distributor.

In the case of laboratories in charge of producing products on behalf of third parties, either in their entirety or in some of the stages of the production process, responsibility for the quality of the product is assumed jointly by them and by the company that owns the Registry.

Distributors and public sales establishments of pharmaceutical products, each in their marketing area, are obliged to preserve and monitor the maintenance of their quality until they are received by users, under responsibility.

Article 58.- Pharmaceutical products that are marketed in the country and others that correspond, must respond in their qualitative and quantitative analyzes to the formula and composition declared by the manufacturer and authorized for their manufacture and sale when the Health Registry is granted.

Article 59.- The quality control of pharmaceutical products and other corresponding products is mandatory, comprehensive and permanent. To guarantee their quality, manufacturing companies, under their responsibility, must have a quality control system that covers all aspects of the manufacturing process, from the raw materials used to the finished products.

Article 60.- The National Health Authority is responsible for monitoring the quality of the products included in this Chapter. Control is carried out through inspections of manufacturing, distributing and dispensing companies and the execution of analyzes of samples of investigated products at any of their stages of production, distribution and sale.

Article 61.- Narcotic drugs, psychotropic drugs and precursors for medical use included in the International Conventions on the subject and those determined by the

National Health Authority, are governed by this law and its special legislation.

Article 62.- The Health Authority at the national level establishes a list of medicinal plants with restricted or prohibited use due to their toxicity or danger.

Article 63.- The marketing of medicinal plants and their preparations obtained in the form of extracts, freeze-dried, distilled, tinctures, decoctions or any other galenic preparation with therapeutic, diagnostic or preventive purposes in the condition of master formulas, official preparations or medications, is subject to the requirements and conditions established by the regulations.

Medicinal plants that are offered without reference to therapeutic, diagnostic or preventive properties can be freely marketed.

Article 64.- Natural or legal persons who are dedicated to the marketing of pharmaceutical products to carry out their activities must comply with the requirements and sanitary conditions established in the regulations, and adhere to the Good Storage and Dispensing Practices dictated by the Authority of National level health.

The Health Authority at the national level or to whomever it delegates, will periodically verify compliance with the provisions of this provision.

Article 65.- The outpatient sale of pharmaceutical products is prohibited.
With the exception of the provisions of subsection d) of Article 68 of this law, the trade of pharmaceutical products may only be carried out in pharmaceutical establishments, which must be under the responsibility of a professional pharmaceutical chemist. In places where there are no pharmaceutical chemicals in sufficient numbers, what is established in the regulations will be followed.

Article 66.- The chemical-pharmaceutical professional who assumes the technical direction or management of any pharmaceutical establishment is responsible for everything that affects the identity, purity and good condition of the products that are manufactured, prepared, manipulated, stored or supplied in them.

Likewise, they are responsible for ensuring that the distribution or acquisition of pharmaceutical products in the establishments they direct or manage is only carried out at and in pharmaceutical establishments, as the case may be.

The responsibility of the technical director or regent does not exclude, in any case, the responsibility of the pharmaceutical establishment.

Article 67.- Medicines must be identified with their brand name if they have one, and with their International Common Name (INN), established by the World Health Organization.

They may not be registered as trademarks to distinguish medicines, INNs or other names that may be confused with them.

Article 68.- The national Health Authority will classify pharmaceutical products for the purposes of their sale into the following categories:

a) For sale with presentation of a special numbered prescription, which can only be dispensed in pharmacies and pharmacies, which will comply with the requirements determined by the international conventions to which Peru is a party, the law on the matter and its regulations;

b) For sale under a medical prescription that can only be dispensed in pharmacies and pharmacies;

c) For sale without a medical prescription that are sold exclusively in pharmacies and pharmacies; and,

d) For sale without a medical prescription that can be marketed in non-pharmaceutical establishments.

Article 69.- Pharmaceutical products that have a Health Registry in the country and authorized for sale without a medical prescription may be advertised through media available to the general public.

In addition to the provisions of the general rules on advertising in defense of the consumer, the advertisement intended for the general public must not contain exaggerations about its properties that may mislead the consumer.

Only by exception and in response to duly justified reasons, the national Health Authority may determine the pharmaceutical products sold under medical prescription that may be advertised through means that are within the reach of the general public. In this case, the advertising will refer the consumer to read the instructions contained in the leaflet or insert that accompanies the pharmaceutical product.

Article 70.- Advertising on containers, labels, signs, packaging, inserts or leaflets that accompany pharmaceutical products sold under medical prescription is prohibited.

Article 71.- The promotion and advertising of pharmaceutical products authorized for sale under medical prescription is restricted to the professionals who prescribe and dispense them. In the case of graphic advertising, it can only be done through specialized magazines, brochures, prospectuses or any other printed form that contains technical and scientific information.

By exception, the dissemination of introductory announcements and reminders aimed at professionals of the Medical and Pharmaceutical Corps is permitted through media accessible to the general public. The content of the information provided is subject to the regulations that the national Health Authority dictates on this matter.

The information contained in the advertising of pharmaceutical products in general must comply with what is authorized in the Health Registry.

Article 72.- Misleading advertising of medicines is subject to rectification.

Article 73.- Producers and distributors of medicines are obliged to report adverse reactions to the national Health Authority.

that they are aware of and that could have been derived from the use of the medications they manufacture or market, under responsibility.

Article 74.- The national Health Authority collects and evaluates information on the adverse reactions of medicines marketed in the country and adopts the measures that may be necessary to protect the health of the population.

Article 75.- The national Health Authority ensures the rational use of medicines, promoting the provision of essential medicines.

CHAPTER IV

OF NATIONAL AND INTERNATIONAL CONTROL OF DISEASES TRANSMISSIBLE

Article 76.- The National Health Authority is responsible for directing and regulating actions aimed at preventing the spread and achieving the control and eradication of communicable diseases throughout the national territory, exercising epidemiological surveillance and health intelligence and dictating the corresponding provisions.

Likewise, it has the power to promote and coordinate with people and public or private institutions the carrying out of activities in the epidemiological and health field.

Article 77.- The competent Health Authority is responsible for the control of communicable diseases within its jurisdiction.

Article 78.- The national Health Authority will determine the communicable diseases of mandatory declaration and notification.

All natural or legal persons are obliged to provide said epidemiological information, within the terms of responsibility, classification, periodicity, destination and clarity indicated in the regulations.

Article 79.- The Health Authority is empowered to dictate prevention and control measures to prevent the appearance and spread of communicable diseases. All natural or legal persons, within the territory, are obliged to comply with these measures, under sanction.

Article 80.- Exceptions to mandatory vaccination and revaccination, established by the national Health Authority, may be established only for medical or biological reasons.

Article 81.- The administrative, municipal, military and police authorities, as well as individuals, are obliged to provide the support required by the Health Authority to control the spread of communicable diseases in places in the national territory where they acquire characteristics. serious epidemics.

Article 82.- In the fight against epidemics, the Health Authority is empowered to arrange the use of all medical-care resources of the public and private sectors existing in the affected and adjacent areas.

Article 83.- The Health Authority is responsible for the surveillance and health control of the borders, as well as all sea, air, river, lake or land ports in the national territory.

Article 84.- Temporarily, and only for reasons of public health, the Health Authority may restrict the carrying out of activities for the production of goods and services and commerce, as well as the transit of people, animals, vehicles, objects and articles. that represent a serious risk to the health of the population.

Article 85.- International health services are governed by the provisions of this law, its regulations and the technical standards issued by the National Health Authority, as well as by the international treaties and agreements to which Peru is a party.

Article 86.- Natural or legal persons who work with viruses, fungi, bacteria or their components and, in general, with biological agents dangerous to human health, must comply with the corresponding biosafety measures. Its activities are subject to surveillance by the competent Health Authority.

Article 87.- To avoid the transmission of diseases to people, owners or possessors of domestic, domesticated or captive animals must comply with the health measures determined by the competent Health Authority.

The owners or possessors of animals that transmit diseases to people are responsible to third parties. The production of damage causes the loss of your property or possession, and the competent Health Authority must dispose of it in the manner established by the regulations.

The competent Health Authority has the free disposal of ownerless or abandoned animals even if they do not represent an immediate risk to human health.

CHAPTER V

OF FOOD AND DRINKS, COSMETIC AND SIMILAR PRODUCTS, SUPPLIES, INSTRUMENTS AND EQUIPMENT FOR MEDICAL-SURGICAL USE DENTISTRY, HEALTH PRODUCTS AND PERSONAL HYGIENE PRODUCTS AND DOMESTIC

Article 88.- The production and trade of food and beverages intended for human consumption as well as alcoholic beverages are subject to hygienic and sanitary surveillance, in order to protect health.

Article 89.- A food is legally suitable for human consumption when it meets the characteristics established by the health and quality standards approved by the national Health Authority.

Article 90.- It is strictly prohibited to import, manufacture, divide, process, trade, transfer free of charge, distribute and store altered, contaminated, adulterated or falsified food and beverages.

Article 91.- All industrially produced food and beverages, of national or foreign production, may only be sold after a Health Registration.

Article 92.- The National Health Authority is responsible for the health control of food and beverages, cosmetic and similar products, as well as supplies, instruments and equipment for medical-surgical or dental use, health products and hygiene products. personal and domestic.

The Health Registry of food and beverages, cosmetic and similar products, as well as supplies, instruments and equipment for medical-surgical or dental use, health products and personal and domestic hygiene products, will be automatic with the sole submission of a request. of sworn declaration stating the unified registration number of the applicant natural or legal person, and the certification of free marketing and use, both of which may be recorded in a single document, issued by the competent authority of the country of origin or export of the product.

Registration in the aforementioned Health Registry is automatic, with the sole presentation of the documents established in this provision, the health authority having a maximum period of 7 business days to issue the document that certifies the registration number.

The aforementioned Health Registry is temporary and renewable. The Customs of the Republic will proceed to dispatch the merchandise referred to in this article, requiring, in addition to the general documentation required for importation, only the sworn declaration of the importer stating the health registration number, or failing that, the date of presentation of the corresponding application, as well as the expiration date in the case of packaged foods, which must appear by printing or labeling on the containers for sale to the consumer, together with the company name and Unified Registry of the importer or general distributor.

The outpatient sale of supplies, instruments and equipment for medical-surgical or dental use is prohibited.

Article 93.- The importation of any food or beverage whose trade, distribution and consumption is not permitted in the country of origin is prohibited because it constitutes a risk to health.

Article 94.- Personnel involved in the production, handling, transportation, conservation, storage, sale and supply of food are obliged to do so under hygienic and sanitary conditions to avoid contamination.

Article 95.- The manufacture, preparation, fractionation, storage and sale of food and beverages must be carried out in premises that meet the conditions of location, installation and sanitary operation, and comply with the requirements established in the regulations issued by the Health Authority. national level.

The Health Authority at the national level or to whomever it delegates, will periodically verify compliance with the provisions of this provision.

CHAPTER VI

OF SUBSTANCES AND PRODUCTS DANGEROUS FOR HEALTH

Article 96.- In the import, manufacturing, storage, transportation, trade, handling and disposal of dangerous substances and products, all necessary measures and precautions must be taken to prevent damage to human, animal or environmental health, in accordance with the regulations. corresponding.

Article 97.- When the import, manufacturing, transportation, storage, trade and use of a substance or product is considered dangerous for the health of the population, the State must establish the corresponding protection and prevention measures.

Article 98.- The competent Health Authority dictates the rules related to the qualification of dangerous substances and products, the conditions and limits of toxicity and danger of said substances and products, the requirements on information, packaging, containers, packaging, transportation, labeling and other aspects required to control risks and prevent damage that these substances and products may cause to people's health.

Article 99.- Waste from establishments where dangerous substances and products are manufactured, formulated, packaged or handled must be subjected to the treatment and disposal indicated in the corresponding regulations.
Said waste should not be dumped directly into water sources, courses or reservoirs, into the ground or into the air, under responsibility.

Chapter VII

OF HYGIENE AND SAFETY IN WORK ENVIRONMENTS

Article 100.- Those who conduct or manage activities of extraction, production, transportation and trade of goods or services, whatever they may be, have the obligation to adopt the necessary measures to guarantee the promotion of the health and safety of workers and of third parties in their facilities or work environments.

Article 101.- The hygiene and safety conditions that workplaces, equipment, machinery, facilities, materials and any other element related to the performance of extraction, production, transportation and trade of goods or services must meet. They are subject to the provisions dictated by the competent Health Authority, which will monitor compliance.

Article 102.- The hygienic and sanitary conditions of all work centers must be uniform and in accordance with the nature of the activity carried out without distinction of rank or category, age or sex.

Chapter VIII

OF ENVIRONMENTAL PROTECTION FOR HEALTH

Article 103.- The protection of the environment is the responsibility of the State and of natural and legal persons, who have the obligation to maintain it within the standards established by the competent Health Authority to preserve people's health.

Article 104.- Any natural or legal person is prohibited from discharging waste or polluting substances into the water, air or soil, without

having adopted purification precautions in the manner indicated by health and environmental protection standards.

Article 105.- It is the responsibility of the competent Health Authority to dictate the necessary measures to minimize and control the risks to people's health derived from environmental elements, factors and agents, in accordance with what is established, in each case, by law. Of the mattery.

Article 106.- When environmental pollution means risk or damage to people's health, the national Health Authority will dictate the prevention and control measures essential to stop the acts or events that cause said risks and damage.

Article 107.- The water supply, sewage, disposal of excreta, reuse of sewage and disposal of solid waste are subject to the provisions dictated by the competent Health Authority, which will monitor compliance.

TITLE THREE

FROM THE END OF LIFE

Article 108.- Death puts an end to the person. Absence of life is considered the definitive cessation of brain activity, regardless of whether some of its organs or tissues maintain biological activity and can be used for transplant, graft or culture purposes.

The well-founded diagnosis of definitive cessation of brain activity verifies death. When it is not possible to establish such a diagnosis, the finding of irreversible cardio-respiratory arrest confirms death.

None of these criteria that demonstrate by diagnosis or corroborate by verification the death of the individual, may appear as causes of the death in the documents that certify it.

Article 109.- The autopsy is appropriate in the following cases:

a) For clinical reasons, to evaluate the diagnostic accuracy and precision and the quality of patient treatment;

b) For cremation purposes, to determine the cause of death and provide for the disappearance of evidence of the commission of crimes;

c) For health reasons, to establish the cause of death with the purpose of protecting the health of third parties; and,

d) For medical-legal reasons, to determine the cause of death, in cases established by law or when ordered by the competent judicial authority, or to specify the identity of the deceased.

Only necropsy for clinical reasons requires the authorization referred to in Article 47 of this law.

Article 110.- In cases where, by mandate of law, an autopsy must be performed or when the body is embalmed or cremated,

may perform the ablation of organs and tissues for transplant or graft purposes, without requiring authorization given while alive by the deceased or the consent of his or her family.

The disposal of organs and tissues from corpses for the purposes provided for in this provision is governed by this law, the law of the matter and its regulations.

Article 111.- It is only permitted to bury corpses in cemeteries duly authorized by the competent Health Authority, in accordance with the provisions of the relevant law and its regulations.

Article 112. Every corpse that makes the spread of diseases possible shall be cremated before necropsy.

Article 113.- The competent Health Authority is obliged to order the eradication of cemeteries when their location constitutes a health risk.

Article 114.- The corpses of unidentified persons or those who, having been identified, have not been claimed within a period of thirty-six (36) hours after their entry into the morgue, may be dedicated for research or study purposes. For the same purposes, corpses or human remains may be used by the manifest will of the person before death or with the consent of their relatives.

Article 115.- The burial, exhumation, transfer and cremation of corpses or human remains, as well as the operation of cemeteries and crematoriums are governed by the provisions of this law, the law of the matter and its regulations.

Article 116.- The trade in corpses and human remains is prohibited.

FOURTH TITLE

OF HEALTH INFORMATION AND ITS DISSEMINATION

Article 117.- Every natural or legal person is obliged to provide in a correct and timely manner the data that the Health Authority requires for the preparation of statistics, the evaluation of health resources and other special studies that are necessary to carry out and contribute to knowledge of health problems or measures to address them.

Article 118.- In the event of a declared epidemic or danger of an epidemic, the press, radio, television and all other means of social communication must collaborate with the competent Health Authority in the manner provided by the Executive Branch.

Article 119.- Information, propaganda and advertising that refers to health, the treatment of diseases, rehabilitation, the exercise of health professions and services referred to in this law, must not induce conduct. , harmful practices or habits that imply a risk to physical or mental health, nor distort or contravene the provisions established by the Health Authority regarding the prevention, treatment or rehabilitation of diseases.

Without prejudice to the provisions of the general advertising regulations in defense of the consumer, advertising regarding the provision of health services may not offer preventive, curative or rehabilitative treatments whose effectiveness has not been scientifically proven.

Article 120.- All health information that Public Sector entities have in their possession is in the public domain. Exceptions are information that may affect personal and family privacy or self-image, national security and foreign relations, as well as information that refers to aspects protected by industrial property regulations in accordance with the law on the matter.

Article 121.- It is the obligation of the competent Health Authority to warn the population, through the most convenient channels and means that best suit the circumstances, about the risks and damages that certain products, substances cause or may cause to health. or activities.

TITLE FIVE

FROM THE HEALTH AUTHORITY

Article 122.- The Health Authority is organized and exercised at a central, deconcentrated and decentralized level.

The Health Authority is exercised by the bodies of the Executive Branch and the decentralized bodies of government, in accordance with the powers conferred on them by their respective laws of organization and functions, organic laws or special laws in the field of health.

Article 123.- It is understood that the National Health Authority is the specialized body of the Executive Branch that is responsible for the direction and management of the national health policy and acts as the highest regulatory authority in matters of health.

Article 124.- In application and compliance with the health standards dictated by the Health Authority at the national level, the decentralized or decentralized bodies are empowered to provide, within their scope, prevention and control measures of a general or particular nature in the matters of its competence.

Article 125.- The decentralized exercise of control powers in health matters does not imply, in any case, the exercise of regulatory jurisdiction, unless otherwise stipulated in the law itself.

The delegation of control powers in health matters does not imply, in any case, the delegation of regulatory powers.

Article 126.- Norms that regulate laws or that have equivalent hierarchy, that affect health matters, may not be dictated without the endorsement of the National Health Authority.

Article 127.- Public entities that, due to their laws of organization and functions, organic laws or special laws, are empowered to control health and environmental aspects, are subject to supervision by the National Health Authority.

Likewise, the Professional Associations of the health sciences are subject to supervision by the National Health Authority, only with regard to the surveillance that they carry out on the activities that their associates carry out in the exercise of their profession.

Article 128.- In the use of the powers conferred upon it by this law, the organic laws, the laws of organization and functions, other special laws and their regulations, the Health Authority is empowered to provide guidance and educational actions, practice inspections on any movable or immovable property, take samples and carry out the corresponding tests, collect information and carry out other actions that it considers relevant for the fulfillment of its functions, as well as, if applicable, apply security measures and sanctions.

Article 129.- The Health Authority may request the assistance of public forces to ensure compliance with the provisions and measures adopted to protect health.

TITLE SIX

OF SECURITY MEASURES, INFRINGEMENTS AND SANCTIONS

CHAPTER I

ABOUT SECURITY MEASURES

Article 130.- The following are security measures:

a) Isolation;

b) Quarantine;

c) Personal observation;

d) Vaccination of people;

e) Animal observation;

f) Vaccination of animals;

g) The destruction or control of insects or other transmitting and harmful fauna;

h) The confiscation or sacrifice of animals that constitute a danger to the safety or health of people;

i) The suspension of work or services;

j) The issuance of advertising messages that warn of danger of damage to the health of the population;

k) The confiscation, seizure, immobilization, withdrawal from the market or destruction of objects, products or substances;

l) The temporary suspension of the exercise of production and trade activities and the restriction of the transit of people, animals, vehicles, objects and articles;

ll) The temporary or permanent closure of companies or their facilities;

m) Suspension or cancellation of the Health Registry; and,

n) Others that, in the opinion of the Health Authority, are considered health-justifiable, to prevent risk or damage to the health of the population from being caused or continuing to be caused.

Article 131º.- Security measures are immediately executed and are applied without prejudice to the corresponding sanctions.

Article 132.- All security measures adopted by the Health Authority in application of this law are subject to the following principles:

a) They must be proportional to the purposes pursued;

b) Their duration must not exceed what is required by the situation of imminent and serious risk that justified them; and,

c) Preference should be given to those measures that, being effective for the purpose pursued, do the least harm to the principle of free movement of people and goods, freedom of business and any other affected rights.

Article 133.- The regulations establish the procedure for the application of the security measures referred to in this Chapter.

Chapter II

OFFENCES AND PENALTIES

Article 134.- Without prejudice to any civil or criminal actions that may arise, violations of the provisions contained in this law and its regulations will be subject to one or more of the following administrative sanctions:

a) Warning

b) Fine

(c) Temporary closure or closure of the establishment; water,

d) Suspension or cancellation of the Health Registration of the product.

Article 135.- When imposing a sanction, the Health Authority will take into account:

a) Damage that has occurred or may occur to people's health;

b) The seriousness of the infraction; and,

c) The condition of recidivism or repetition of the offender.

Article 136.- Any sanction of closure and temporary closure of establishments, as well as suspension or cancellation of Health Registration of products, must be published, at the expense of the offender, by the Health Authority in the manner established by the regulations.

Article 137.- The regulations establish the classification of infractions, the scale of sanctions and the procedure for their application.

COMPLEMENTARY, TRANSITIONAL AND FINAL PROVISIONS

First.- The establishments referred to in Article 37, the establishments dedicated to the activities included in Articles 56, 64, 95, 96 of this law, as well as funeral agencies, wakes and other funeral services related to these do not They require health authorization for their authorization or operation.

Second.- The national Health Authority determines the fee for health registration, which may not exceed 10% of the Tax Unit. The income from this concept will be used exclusively for inspection and quality control actions.

Third.- In cases of sudden or accidental death, and as long as the exchange of the Electoral Book for the National Identity Document referred to in Laws Nos. is not completed. 26497 and 26745, the positive will of the deceased to donate his organs or tissues for transplant or graft purposes is presumed, without proof to the contrary being admitted.

Fourth.- The following provisions are repealed:

a) Decree Law No. 17505, which approves the Health Code;

b) Decree Law No. 19609, referring to emergency care;

c) Law No. 2348, of November 23, 1916, on Declaration, Isolation and Mandatory Disinfection of Diseases;

d) Law on the Practice of Medicine and Pharmacy, dated November 28, 1888;

e) Decree Law No. 25596, which establishes the requirements for obtaining the Health Registry and Authorization for the import and marketing of generic and brand-name medications;

f) Third Complementary Provision of Decree Law No. 25988, on health card, as well as any legal, administrative and technical provision that establishes the obligation to obtain and carry a health card or similar document, and

g) Others that oppose the provisions of this law.

Fifth.- The Ministry of Health, within a maximum period of thirty (30) days, counted from the effective date of this law, will present, for approval, the regulations required for the execution of the provisions of this law. .

Sixth.- This Law will come into force one hundred and eighty (180) calendar days after its publication, with the exception of Chapters III and V of the Second Title, which govern from the day following the publication of this Law.

Please inform the President of the Republic for its promulgation.

In Lima, on the ninth day of the month of July, one thousand nine hundred and ninety-seven.

VICTOR JOY WAY ROJAS

President of the Congress of the Republic

CARLOS TORRES AND TORRES LARA

First Vice President of the Congress of the Republic

TO THE CONSTITUTIONAL PRESIDENT OF THE REPUBLIC

THEREFORE:

I order it to be published and fulfilled.

Given at the Government House, in Lima, on the fifteenth day of July, one thousand nine hundred and ninety-seven.

ALBERTO FUJIMORI FUJIMORI

Constitutional President of the Republic

ALBERTO PANDOLFI ARBULU

President of the Council of Ministers

MARINO COSTA BAUER

Health Minister