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**DRAFT BILL FOR THE FRAMEWORK ACT ON SUPPLEMENTARY MEDICINES**

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## CONTEXT

During the two last decades, Latin America as the rest of the world has witnessed the emergence of a wide social demand with respect to the use of different clinical therapeutical and health enforcement models generally known as supplementary or alternative medicines. In some countries, there are data about the percentage of the population that uses them, even as the first option in the treatment of health problems, what has generated an increasing number of new users.

The lack of research and academical sustainability of many of them is evident, as well as the lack of sanitary regulation mechanisms, allowing that persons without official recognition or recognized formal education, call themselves alternative physicians, wise men or therapist, deceiving people, resorting to procedures and therapies that, in many cases, may cause health damages, affecting the prestige of formal practitioners and the acknowledgement of these therapies.

In the world, due to the quantity and quality of investigations made and published, some of these clinical therapeutical models have been validated through proved efficiency, safety, cost-effectiveness, adherence to ethical and professional rules and social acceptability criteria, proposed by the World Health Organization; therefore, this organization decided in 2002, to propose a program to take advantage of the contributions and limit the risks.

At the 56° World health assembly of the WHO held on May 28, 2003, in its item 14.10, it was decided: “to urge the Member States -according to the legislation and the established national mechanisms- to: Adapt, adopt and apply the strategy of the WHO on traditional, supplementary and alternative medicine as the basis of the national programs on traditional, supplementary and alternative medicine; where applicable, to elaborate and apply national policies and regulations on traditional, supplementary and alternative medicine in order to support the convenient use of traditional, supplementary and alternative medicine and its integration into the national health care systems, according to the circumstances of their countries; to establish systems for the surveillance of drugs safety in order to control herbal medicines and other traditional practices, or to enhance and strengthen the existing systems; to provide reliable information on traditional, supplementary and alternative medicine to consumers and providers with the purpose of promoting there idoneous use, where applicable, to monitor the safety, efficiency and quality of herbal drugs, establishing national standards to herbal raw materials and preparations of traditional medicine, or publishing monographies to this end; to foster, where applicable, the inclusion of herbal drugs in the national list of essential drugs, focusing on the shown needs of the public health of the country and on the verified safety, quality and efficiency of these drugs; to promote, where applicable, the teaching of supplementary medicine at medicine schools”.

Taking into account that the Latin American Parliament is a regional agency, the essential objective of which is the achievement of Latin American integration and the study, analysis and elaboration of policies directed to give an answer to the social problems of the Latin American community, it is the natural space from which this Framework Act on Supplementary Medicines may be promoted, establishing as its purpose the formulation of integral and necessary strategies within the framework of the cultural law, intercultural health and promotion and development of new models of health care, in order to determine the actions taken in this sense by the legislator of each country of the region

## BACKGROUND

At the sessions of the Health Committee of the Latin American Parliament held in Sao Paulo, Brazil, on March 2007 and in the Dominican Republic in March 2009, Mexico submitted the document “Towards the building of a Framework Act for traditional and supplementary medicines for Latin America”.

In the last event, Mexico, through its Office of Traditional Medicine and Intercultural Development, committed before the Health Committee of the Latin American Parliament to prepare a draft bill of a framework act on traditional and supplementary medicines.

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# DRAFT BILL FOR THE FRAMEWORK ACT ON SUPPLEMENTARY MEDICINES

## I. DEFINITIONS

For the purposes of this act, it is considered that:

- **Supplementary medicines** Also called *alternative, non conventional or parallel medicines*, mean those clinical therapeutical and health strengthening models not integrated to the institutional sanitary system or based on a world vision or cosmovision different from that of the conventional medicine model and that are not part of the traditional medicines of each country.
- **Homeopathics** mean the therapeutical clinical medical system based on the similarity and infinitesimals rule, that says that disease may be treated with very small quantities of vegetal, animal and mineral substances that in greater quantities may produce in a healthy person the same symptomatic effects proper of the disease. The role played by emotions in diseases is deepened, assigning to it a decisive importance in the diagnostical and therapeutical procedures.
- **Acupuncture** means a therapeutical clinical model that does not use drugs, based on the stimulation of different points of the human body placed in channels called meridians, through the insertion and manipulation of metallic sterilized needles and other related methods. It implies an integral cosmovision of the human being, that derives from Chinese traditional medicine or east sino medicine with the application of diagnostical and therapeutical methods of stimulation of energetic points of the body, through different traditional and modern technologies. Acupuncture related methods mean those methods on which human acupuncture practice is based: Electrostimulation, laser stimulation, moxibustion, magnets, ultrasound, massotherapy, ventoses, three-edged needles, tacks, pellets and seeds.
- **Chiropractic** means the therapeutical clinical model which deals with the diagnosis, treatment and prevention of disorders of the muscle skeletal system, and its effects on the nervous system and on the health in general, using body manipulations and other strategies directed to restore functional normality and, in this way, counteract the underlying disease.
- **Medicinal herbology** means the use of medicinal plants with therapeutical purposes that may be curative or even preventive.
- **Informed consent letter** mean *written documents* signed by the patient or his legal representative, in which he accepts, after being duly informed, the expected risks and benefits, with diagnostical, therapeutical or rehabilitation purposes.

## II. GENERAL PROVISIONS

Purpose and application scope

- The purpose of this framework act is to establish guidelines for the regulation and modulation of the practice, training and investigation of supplementary medicines in order to determine the necessary steps as regards surveillance and safety for society in terms and conditions that allow its development according to the legislation established by the countries in the sphere of health, promoting the necessary legislative changes or adjustments and those required in extraordinary situations, as a basic element for the full exercise of the Right to Health Protection.
- It aims at enhancing the health care of Latin American population, taking advantage of the clinical therapeutical and health strengthening models that comply with the criteria of safety, proved efficiency, cost effectiveness, adherence to ethical and professional rules and social acceptability, established by the WHO.
- This Act shall ensure the right of the population to resort to the government jurisdiction to protect its preference with respect to the use of different clinical therapeutical non conventional

models, in safety conditions.

- The provisions of this Act are of public interest, preferential enforcement and compulsory compliance at health institutions of public, private and social sectors.

Application scope:

It shall be compulsory for natural and legal persons of public, social and private sectors, including medical offices that use validated Supplementary medicines and related methods in the terms foreseen in this Act.

- It orders to:
  - Define strategies to provide information to the general population about the efficiency and harmlessness of the different practices and products recognized in the legal framework, and about their contraindications in order to assess the quality of the services received, both from the supplementary and conventional medicines.
  - Establish the adequate channels to allow users to report adverse reactions derived from the use of these therapies and inform about those channels.
  - Regulate training and knowledge requirements of practitioners and professionals of these clinical therapeutical and health strengthening models so that they have the adequate qualifications according to specific competence models.
  - Encourage the interaction between practitioners and professionals of traditional, supplementary and institutional medicines.
  - Promote the inclusion of supplementary medicines in medical insurance, as well as non conventional therapies and products with solid evidences that establish the mechanisms for the generation of services quality records, defined by the Health Services.
  - Define processes and structures of the health system that would promote the improvement of quality and safety.
  - Establish quality standards and treatment guidelines to ensure uniformity within a determined health system.
  - Favor cooperation among providers of conventional and supplementary primary care in order to improve the treatment results and foster the reform of the health sector.
  - Favor the organization of professionals and technicians of supplementary and alternative medicines in order to give a better structure to self-control mechanisms.

### III. POWERS OF THE HEALTH DEPARTMENTS

The Health Department shall have the following powers:

- To be in charge of the National Program of Non Conventional Clinical Therapeutical and Health Strengthening models (Supplementary Medicines).
- To adapt, adopt and apply, where applicable, the WHO strategy on supplementary medicines as a basis of the national programs on supplementary medicines.
- To recognize, incorporate, regulate and promote the development of clinical therapeutical and health strengthening models which comply with safety, proved efficiency, cost-effectiveness, adherence to ethical and professional rules and social acceptability criteria. For this purpose, it shall be necessary to limit their sphere of action, to specify practitioners profile, the scope of their actions, the definition of their subject matter and their therapeutical resources.
- To develop the required legal instruments and rules, with the participation of supplementary medicines professionals and practitioners for their definition and instrumentation.
- To define validation mechanisms and corresponding instances as well as the necessary

measures for the surveillance and regulation of supplementary medicines.

- To develop and apply national policies and regulations on supplementary medicine to support the adequate use of supplementary medicines and their integration into national health care systems, according to the circumstances of their countries;
- To establish safety surveillance systems for supplementary medicines or extend and strengthen the existing systems;
- To give adequate support to the research on supplementary medicines.
- To provide reliable information on supplementary and alternative medicine to users and providers with the purpose of promoting their convenient use.
- To include herbary and homeopathic drugs as well as inputs and equipment used by acupuncture, in the national list of essential drugs, inputs and equipment, focusing on the proven needs of the public health of the country and on the verified safety, quality and efficiency of those inputs.
- To promote the inclusion in the catalogs of specialties and medical staff of human resources, where applicable, of the different types of professional resources who use supplementary medicines and who are registered and professionalized in each country.
- To promote the teaching of the different clinical therapeutical and health strengthening models at medicine schools.
- To participate together with other Government agencies in the proposal of policies for the import, production, trade, prescription and use of all those inputs, material and equipment that may affect human health: drugs, instruments and equipment of medical use and application.
- To ensure the processes for the communication, exchange and collaboration among Latin American countries to share information that allows the achievement of scientific validations; elaborate common use criteria, define common criteria for the professionalization of teaching and collaborate to define, if possible, a common regulatory framework.
- The other necessary powers for the fulfillment of their functions, or those assigned by law.

#### IV. ABOUT RESEARCH AND VALIDATION

- According to the regulatory framework of each country, the recognition and incorporation into the National Health System of clinical therapeutical and health strengthening models -which comply with safety, proved efficiency, cost-effectiveness, adherence to ethical and professional rules and social acceptability criteria- shall be promoted.
- Each country shall define the agency in charge of the implementation of the validation of supplementary medicines, taking advantage of the research made in its own country, as well as the investigations and validation processes carried out by the other countries of the Latin American region and the world.
- The recognition of a supplementary medicine shall be granted by the agency of the National Health System defined to that end, based on the proved contributions and benefits of the model for the National Health System, shown by the validating agency, taking into account the referred criteria.
- The national mechanisms for the promotion of the research on the efficiency of supplementary medicines shall be implemented and/or strengthened, taking into account its sociocultural view as well as its scientific validation.
- The articulation with the countries of the Latin American region shall be implemented in order

to define strategies that allow shared validation processes.

- The models of Acupuncture, Homeopathics, Chiropractice and medicinal Herbolary, that are already recognized by the WHO, that have scientific validation and are already institutionalized in some countries of Latin America and the world, should be recognized as supplementary medicines and incorporated in the National Health System.

## V. ABOUT PROFESSIONAL TRAINING

The corresponding education and health authorities of each country shall:

- Promote the teaching of the different clinical therapeutical and health strengthening models at medicine schools.
- Define the minimum requirements for the professional teaching of the different clinical therapeutical and health strengthening models validated and incorporated into the legal framework.
- Elaborate and propose the criteria for the assessment of education programs and curricula of the health area careers, at the different academical levels of each discipline, based on the applicable rules and on the education and health policies, in order to establish a training and education based on the capacities necessary for the excellent performance of these professionals and technicians.
- Elaborate indicators and criteria which contribute to the recommendation of requirements to allow public and private health institutions to participate in the training of health human resources in these disciplines.
- Collaborate with the corresponding authorities of other countries for the exchange and homologation of those criteria.
- Ensure that the educational institutions which incorporate these criteria and programs assess and certify graduates and issue and register the corresponding professional license.
- Grant the educational recognitions, through a certificate of an institution recognized by the Education and Health Department.
- Develop training activities directed to improve the education of the professionals and technicians of supplementary medicines through congresses, workshops, forums and intercultural meetings, with respect to elements of the health programs in the areas of Acupuncture, Homeopathics, chiropractice, medicinal herbolary and Primary Care.

## VI. ABOUT RECOGNITION OF PROFESSIONALS AND TECHNICIANS WHO PRACTICE SUPPLEMENTARY MEDICINES.

- Each country shall define the existence and professionalization of the medical and technical staff in supplementary medicines incorporated in their legal framework who have a certified and professionalized training system.
- The medical accupuncturist or the physician especialized in acupuncture shall be responsible for the treatment with acupuncture.
- The homeopathic physician or the physician especialized in homeopathics shall be responsible for the treatment with homeopathics.
- The chiropractice professional shall be responsible for the respective treatment.
- The degrees, professional medical licenses or professional technician licenses and the

specialization documents of these professionals shall be legally issued and registered by competent educational authorities.

- The technical staff shall comply with the requirements established for this purpose by the Public Education Secretariat or Department of each country.
- The control of the supplementary medicines professionals shall be made through a National Professions Register. For the technical staff, a state or regional agency of the Health Department shall be appointed to control the registration of technicians who –in the opinion of the corresponding organizations- have completed educational and training programs. The registers shall be submitted to the governmental agency together with the documents that support them. Such governmental agency shall grant to registered persons a document containing the beforementioned information as well as the number and date with which it was registered, signed and sealed by the corresponding authorities. The responsible agency of the Health Department shall promote the recognition of this register in a National System of Health Information.

## VII. DUTIES OF SUPPLEMENTARY MEDICINES PROFESSIONALS AND TECHNICIANS

- Certified physicians and technical therapists shall have all the prerogatives and rights proper of the other health sciences professionals of their same level, both at the public and private practice and in the access to training and specialization processes.
- The practice of acupuncture, homeopathics, chiropractic, herbolar medicine and other supplementary medicines validated in the legal framework of each country shall be made with therapeutical purposes and based on the scientific and ethical principles that govern the medical practice, according to the medical legal framework of each country.
- The equipment, instruments, material and other inputs necessary for health care - used in the practice of acupuncture, homeopathics and recognized supplementary medicines- shall be subject to the verification and registration of the Health Department, notwithstanding the powers of other corresponding agencies.
- Physicians and technical therapists certified for practicing a determined non conventional clinical therapeutical and health strenghtening model shall :
  - Be registered before the sanitary authorities through the corresponding national mechanisms.
  - Comply with the standards applicable to acupuncture, homeopathics, chiropractic and medicinal herbolar determined by other established official rules and other applicable provisions.
  - Prepare a clinical record of patients in the terms foreseen in the Official Rules or medical regulations applicable to clinical records.
  - Comply with the rules established with respect to the space and sanitary characteristics of the premises used.
  - In the cases of first-time patients, an informed Consent Letter shall be made, and it shall be subject to the requirements foreseen in sanitary provisions. It may be revoked while the procedure for which it was granted is not initiated and it shall not oblige the doctor to follow or omit a procedure when there is an unjustified risk for the user.
  - Fulfill their duties with responsibility, monitoring users safety and their national register as a Health Services input.
  - Collaborate and participate in public health programs, with emphasis in primary care items.

- Report to the nearest health authority the cases of patients with transmissible, infectious and incurable diseases and the cases in which public servants do not take resolute steps when being notified of such circumstances.
- Refrain from following a treatment to patients who cannot be treated or when the treatment may represent a risk with this kind of medicine.
- Submit written or oral reports on their activity at the request of health authorities.
- Have a register of their activities and patients and submit a yearly report before the respective Sanitary Unit.
- Inform about a change of address.
- They may be summoned to take part in Health Programs, during national mobilizations.

## VIII. ABOUT THE INTERRELATION AND INTEGRATION WITH HEALTH SERVICES

- Health Departments shall establish the mechanisms necessary for supporting the regulatory and operative structure for the innovation and development of supplementary medicines, in the areas of planning, innovation or medical care, according to the conditions and characteristics of each country in order to establish implantation strategies that involve the capacity to encourage regulatory changes as regards staff hiring, infrastructure building, operation regulations, procedures handbooks and any related regulation for the development of the practice of these medicines. Likewise, it shall define the financial schedule of the necessary resources for the establishment of pilot models that allow the visualization and assessment of the services with these innovations.
- The health department shall promote the training and intercultural relation between senior and operative health staff and supplementary medicine professionals, which shall take place within a framework of respect and complementation. For this purpose, the staff of official health units shall be instructed about the kind of relations that shall be established with professionals and technicians of supplementary medicines remarking the mutual respect and support, specifying the attitudes to be eradicated (contempt, mockery and discrimination).
- For this reason, the health staff that designs and operates programs of interrelation with supplementary medicines shall be trained in order to have an intercultural vision and the labor and/or professional skills determined by the Health Department.
- The Health Department shall propose the agency that shall coordinate at national level the policies, activities, processes and programs related to supplementary medicines, in order to encourage the coordination and services strengthening.
- The Health Department may sign agreements with professional and technicians of supplementary medicines defining mutual participation programs that include the required skills to participate in the program.

## IX – CONTROL REGISTERS

- The Sanitary Units of the country shall hold a register for the control of health care premises that include supplementary medicines services.
- Health Departments shall promote and enhance the registration of inputs used by professionals and technical therapists in order to establish a joint control of the substances used with healing purposes.

- The Health Department shall follow the processes necessary for the register of new technologies and drugs.
- All the modalities used for the trading of these elements shall be controlled by the Health Authorities and, for this purpose, an Official Rule or instrument that determines the involved technical and metrology aspects shall be issued.
- The Health Department shall publish the substances officially authorized annexing the description of their healing properties in order to create a corresponding vademecum or pharmacopoeia.

#### X. SANITARY CONTROL

- The National Regulatory Authority shall be the agency in charge of monitoring that supplementary professionals are duly certified and comply with national regulations.
- Countries shall look for mutual recognition mechanisms in the region and outside it.

#### XI. FINANCIAL ASPECTS

- Specific budgetary lines for supplementary medicines programs –granted and monitored by the Legislative Power- shall be established.
- It is ensured that resources shall be gradually and irreversibly granted.

#### XII. ASSESSMENT

It shall be compulsory to use, at least, the following indicators:

- Coverage measurement;
- Epidemiological surveillance;
- Measurement of the health condition;
- Social protection as regards health;
- National Health Accounts, and
- Technical capacity of human resources.
- Cost-benefit
- Users and providers satisfaction
- Care quality

Reference for the policies definition and for the surveillance of the efficient use of resources that the National Congress assigns to supplementary medicines.

#### XIII. INNOVATION AND DEVELOPMENT

- It includes the creation of fiscal incentives and other promotion mechanisms to encourage the validation and application of clinical-therapeutical models, particularly with respect to diseases which are relevant for the country and Latin America as regards public health matters.
- It encourages the implementation of strategies that favor private investments in research.

#### XIV. INFRINGEMENTS

- To practice supplementary medicines without official recognition.
- To practice supplementary medicines without complying with regulations in force.
- To establish schools for the training of supplementary medicines without complying with the official criteria and requirements issued to this effect.
- To discriminate supplementary medicines therapists at the Health Services.
- To issue false registers and certificates or include false information in them.
- To have an activity which is different from that officially recognized;
- To give an inadequate use to its professional activity, which may be determined in the following cases:
  - When, due to supervening reasons, the practice of the activities implies a risk or danger to the health;
  - When the limits of the recognized activity are exceeded;
  - In the other cases it is so determined.
- Non compliance of the duties established by the Act.

**Mr. Jose**

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