

Regulations of traditional Chinese medicine in Argentina

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Abstract: Traditional Chinese medicine (TCM) has steadily spread and gained followers due to its efficacy not only in treating illnesses but also in preventing them. The theories, which it is based on, have been perfected over time, as it can be proved in the vast bibliography we can find on the subject. In recent decades, acupuncture and TCM have spread throughout the world, which has led to the improvement of these therapies through studies from the medical approach using modern research systems. The World Health Organization (WHO) not only encourages countries to find and classify effective solutions and harmless practices to apply in public and private health services but also supports them with research. In Argentina, there is a number of schools teaching acupuncture and TCM and also many therapists using it as its first o complementary choice in treatment of different illnesses. However, Argentina has no clear regulations for the practice or the training of acupuncture as a healing activity. These two situations coexist and intermingle in the end. In the last years, two drafts have been passed but they have not been approved yet. What is more, lately many countries have improved the theoretical and practical aspects of acupuncture. The need to regulate these practices cannot be delayed anymore. So, we really hope authorities will find the way to regulate this practice, always with the help of the experts.

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Introduction

Until present, Traditional Chinese Medicine (TCM) has constantly spread and it has gained adherents due to its efficacy not only to prevent, but also to treat different illnesses.

The theories, which it is based on, have been perfected over time, as it can be proved in the vast bibliography we can find on the subject. In the VI century, these theories were introduced in the neighbor countries, and it reached Europe in the XVI century.

Recent decades, acupuncture and TCM have been spread all over the world, which has led to the improvement of these therapies through studies from the medical approach using modern research systems.

The World Health Organization (WHO) not only encourages countries to find and classify effective solutions and harmless practices to apply in public and private health services, but it also supports them with its research (1). The 44th World Health Assembly in 1991 highlighted the importance of supporting investigation about acupuncture and its correct use and the member states were urged to introduce control and rules measures in their own countries. "WHO, p. 28"

Once acupuncture was applied abroad, the need to unify the terminology has been of primary importance to simplify the communication between all the fields of application: education, research, clinical practice and knowledge exchange.

The reality of research and regulation of acupuncture in Argentina

Argentina has a republican political system and its organization is federal, this means that there are national and provincial governments that share the same regulations. However, some regions are completely independent.

Regarding professional regulations as well as health issues, the law is both national and provincial and they are

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Figure 1 Flags of United Nations, UNESCO, and WHO.

not confined or limited to one another. The provinces have freedom of decisions in the matter of education as long as there is no third party or morality and public order affected.

Speaking about the regulation of TCM, there is no national law to enforce "strictly speaking", but there are regulations of an administrative nature, such as resolutions issued by the National Health Ministry (2).

Nevertheless, the scarcity of specific rules does not imply our ignorance of existence.

In 2001, a specific regulation (Res. 997/2001 Ministry of Public Health) was promulgated at the national level. This regulation stated "Acupuncture is a practice or procedures that must be considered a Medical Practice act and as such it must be performed only by professionals authorized by the law N° 17.132"¹. Therefore, if acupuncture is said to be an act of medical practice, only physicians are the only ones who can use it within the federal territory and of course acupuncture is considered as part of the "Healing arts".

However, in 2008, the Resolution 859/2008 Ministry of Public Health repeals the assumption of acupuncture as a Medical Practice Act and extends its practice to kinesiologists, physical therapists, makes this regulation more flexible, another health care professional governed by the law N° 17.132 (3). In other words, acupuncture was no longer considered exclusively as an Act of Medical Practice within the Federal Capital and not under the domain of the provinces.

Likewise, we can mention that Law 26.118 – 2006 confirmed an international treaty (Convention on the Protection of Intangible Cultural Heritage) that emerged from the United Nations for Education, Science and Culture Organization (UNESCO). This convention defined *"Intangible Cultural Heritage" worthy of protection and included* thereby Moxibustion and Chinese acupuncture as "Intangible Cultural Heritage of Humanity." (Figure 1).

Although this aspect seems to be irrelevant to the TCM application in Argentina, it is interesting to say that being an International Treaty confirmed by Law 26.118, article rule 75 Inc. 22 of our National Constitution (Constitución de la Nación Argentina) $(4)^2$, it has higher hierarchy than a National Law as long as the National Constitution is respected. So, the value given to TCM in this International Treaty and adding the importance of the recognition of TCM by the WHO, this medicine cannot be included by any means, to quackery. The practice of quackery is forbidden and considered a crime. Taking into account all the above, TCM cannot be considered a false health practice and the use of TCM in Argentina is legal beyond any doubt, health professionals should be free to exercise it at will. Nevertheless, it is debatable if only professionals with legal nationally recognized degrees can practice it.

Administrative regulations can only make clear the competences regarding health care professionals. Besides, they do not imply a limitation to exercise TCM to independent professionals specifically trained in this ancestral medicine.

Provincially, it is mandatory to examine the local legal framework for each province individually.

In this regard, legal references to TCM regulations are scarce and this is a fact at national level. The existing ones, suppose the exercise of this medicine within its scope, but there are no written restrictions for the specific activity.

Namely, Salta province - Dec 2419/2006 declares of provincial interest the "1st Chi Kung seminar for health, rejuvenating and healing energy" (5). Dec. 3402/2007

¹ It was also enforced by the resolution N 899/2001 of the Public Health Ministry, establishing the "Primary Health Attention" including acupuncture as an alternative health practice and not pharmaceutical together with chiropractics, yoga, etc."

² Endorsed by Rep. Arg. in 2006 by National law N°. 26.118.

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established that acupuncture is not covered by the provincial state health insurance (6).

Tucuman province: Res. 519/2007 Provincial Health Ministry authorized health professionals to make turnouts using acupuncture in the Nicolas Avellaneda Clinical Hospital (7).

San Juan province: Law 8556 included in the Provincial Offence Code, indicates that sterilization of material used for acupuncture is mandatory (8).

Santa Fe province: Law 13.437 regulates the exercise of the kinesiologists and physiotherapists, and sets acupressure and acupuncture in their area of expertise (9).

In general terms, these provinces and all the others that are part of the Argentine Republic have similar regulations, for example, the one referring to the lack of coverage under the state health service for acupuncture and similar therapies and to charge for the acupuncture with provincial tax gross income.

In 1982, Cordoba province forbade the practice of acupuncture together with homeopathy and iridology (Law N 6823). However, since 1986 with the enforcement of the Law N° 7514, the Law 6823 was repealed. This is to say that a prohibition repeal necessary implies "contrario sensu" its authorization.³

Finally, it is important to say that in terms of the recognition expressed, Mendoza province is at the forefront in the Argentine Republic. This province has made the professional training official through the state authorization of a "Higher technician in Acupuncture". This means that the degree has a tertiary-level.

At the same time, all students who receive a degree are automatically authorized to exercise professionally acupuncture in their practice. Provincial Health Ministry issued the resolution N° 3892 by which the professionals at provincial level should be registered. This registration started the current year, 2020.

Under the light of this reality, there is no doubt that TCM needs regulation. To do so, it is important to take into account that the TCM has a therapeutic approach completely different from the allopathic medicine. This aspect of TCM is transcendent when regulating its practice, because all previous attempts failed when stated that only health professionals trained under the umbrella of Western medicine could practice TCM. This point of view is at least, biased, prejudiced and corporative.

In 2007, a draft for a National Law was passed. It was given preliminary approval in the Chambers of Deputies. The Senate of the Nation did not approve the law. This first step towards regulation of TCM was severely criticized by the doctors' corporations that not only took part but also interfered with their prejudices and tried to be given the right of practice only to doctors whether they are appropriately trained or not.

In 2004, some organizations started to work on a new bill to be passed at national level, but this time it was not treated by the congress either.

It is clear that to achieve this goal, acupuncture and TCM educational institutes should be promoted and supported. This action will result in the official recognition of the degree obtained and then the regulation of the professional practice of the related activities. Of course, the lack of a legal framework is far from being positive, because seriously trained professionals must exercise TCM.

Again, the key to succeed is the inclusion of adequately qualified people, not only by organizations and institutions, whether they are included in the legal system of education or not, but also by foreign institutions, until our national education system could offer related careers officially authorized.

What is more, there are no written laws for the different practices related to Chinese medicine. We can name, among others, Moxibustion, Tui Na, Chi Kung. Properly trained personnel and therapists are able to use these techniques if they can demonstrate an adequate training received locally or abroad. Certifications of university degree do not apply here because Argentina does not offer an official training in Qi harmonization techniques. This is why those practices included in TCM are part of the sphere of freedom quoted in the National Constitution Art.19.⁴

Regulations and present reality in Argentina regarding the professional practice of acupuncture

In our country, two different situations coexist which intermingle at the end. In the first place, there is the

 $^{^3}$ Law Nro. 6222 de Córdoba – See arts. 1°; 2° y 7°

⁴ National Constitution - Art. 19°: Men's private actions that are not in any way offensive to the public moral and order, neither cause harm to others, are only under God consideration and they are free from authority of Judges. No one inhabiting our nation is forced to do any action not commanded or deprived of that not forbidden by the law.

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education field, related to the teaching of acupuncture and traditional medicine. Secondly, there is the use of such techniques in the health system in patients.

First, there is no controlling organism that may set the requirement and demands for the creation of the curriculum, teaching load or time required for practice for educational institutions. Besides, there are not requirements for those who teach the subjects included in the study programs either. Yet, some years ago, Mendoza has started a "Higher Technician degree" (10). The degree obtained is not a university degree but it is officially recognized and thus authorizes all undergraduates to exercise acupuncture professionally inside their province. This is why Mendoza is ahead of all other provinces of the Republic of Argentina regarding the professional exercise of acupuncture.

In the second case, the use of acupuncture and TCM with patients the situation is quite similar. This is because there is no controlling authority to require the demands for the professionals that implement this praxis or for the facilities where it is finally applied.

In spite of this lack of scarce regulation, we must not ignore reality. Since long, different therapists use TCM in their private consulting rooms and this activity is recognized by the state, not for all kind of diseases, but only to treat mainly pain and caused by contractures and accidents.

We can mention here, Res. 899/2001 where the Health Ministry issued the "Primary Health-Care Attention Guide" including Acupuncture as a no pharmacological alternative therapeutic practice together with chiropractic, yoga, etc. (11).

Despite the lack of regulation, and with therapists using Acupuncture and TCM without any kind of state control, we must not forget that Argentina is part of the WHO. In 1989, the WHO called a group of scientists that approved an international normalized nomenclature which has been widely applied. This group of scientists also recommended to the International Organism to establish a series of declarations and guidelines on acupuncture regarding the basic training, security in clinical practice, indications and contraindications and clinical investigation (12).

Finally, the WHO regional office for the Western Pacific published a work called "Guidelines for the clinical investigation in Acupuncture" in 1995.

Such guidelines include the basic requirements for acupuncturists' education not only for physicians willing to use it in their daily practice, but also for those who are not medical professionals.

They also aimed to help national health authorities to create norms that rule formal examinations, and set the bases for the creation of study programs for those health institutions that intend to provide education regarding acupuncture or TCM (12).

These recommendations focused on standards to reduce to a minimum infection risks or unintended accidents, to warn acupuncturists about the contraindications and to provide guidance to face the possible complications that may appear during a treatment with these techniques.

The WHO, as the highest authority in world's healthrelated matters, maintains that acupuncture when applied by competent and responsible therapists, is a safe procedure and it has almost no contraindications or complications.

Acupuncture and TCM have grown in popularity around the globe. This fact has aroused the interest in many countries to introduce these therapies in their national health system. This is why national health authorities must ensure the security and the competence wherever and whenever TCM is used in the treatment of people.

Many nations have TCM and Acupuncture as part of their official educational system. These countries have included the aforementioned practices in their public and private institutions as a current part of their health system. To achieve this, there are training programs that last at least four years on university level and the necessary mechanisms have been implemented to control the use of Eastern medicine by qualified professionals.

On the other hand, where "modern Western medicine" is the leading and usually the only foundation of their national health system, the situation is completely different. Sometimes there are not educational framework, professional or legal regulations that determine the practice of acupuncture.

For all the reasons above mentioned, the WHO issued a document entitled "Strategies for the 2002 and 2005" and it has recently made a new contribution via a document entitled "WHO, strategies about traditional medicine 2014–2023" in an effort to change this panorama (13). This report includes not only guidelines and strategies, but also sets a number of goals where WHO strongly recommends taking advantage of the many benefits and contributions of eastern medicines provided for the wellness and health care. They encourage the development of rules to secure its correct use, fostering investigation programs, and introducing products, professionals or practices in the health care system as applicable.

However, most countries have not formally recognized acupuncture. Thus, the rules and requirements, if they exist, vary considerably from one another. In some places,

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qualified physicians are the only ones authorized to practice TCM, while in others personnel trained in traditional medicine whether or not they have a university degree are also allowed to use acupuncture in their practices.

Therefore, it seems quite useful to set a regulatory framework to satisfy the above-mentioned guidelines which sets the limits based in well-designed rules in order to guarantee the safety and competence of the people who have received the training, developing this activity as "acupuncturists or therapists specialized in traditional Chinese medicine".

In order to use acupuncture to its main potential it is important to train professionals properly in the principles of eastern diagnose system.

In order to achieve this goal, the level of training must not only be adequate but also ruled by the local authorities, creating technical degrees and bachelor degrees in both private and public education systems.

The authorities should also regulate the postgraduate courses given to nurses, doctors, kinesiologists and other health care personnel who want to include acupuncture or Chinese medicine as complementary in their daily practice along with Western medicine.

In the last decades, a number of countries have perfected the theories and practices of acupuncture. Hopefully a set of rules would help educational and health authorities to regulate this profession.

Regulations and reality of Chinese phytotherapy

Many Chinese and Western scientific organizations have proved the effectiveness of Chinese phytotherapy. This is the reason why today it is considered as a science and it has been highly recommended for treatment in a number of illnesses for decades, by the WHO.

In China, 70% of ill people is treated with Chinese herbal preparations (Chinese phytotherapy). In this culture, the prescription of herbal preparations is part of the recommendations along with acupuncture (14). There is no doubt that the treatments using this combination are much more effective than acupuncture itself.

When referring to phytotherapy there is no specific norms that regulate it in Argentina. However, the use of this therapy is under the same umbrella as acupuncture. Herbal preparations should be considered food supplements aiming to regulate the Qi and not as medicines.

The "Drug, Food and Medical Technology National Administration" is an organization dependent of the national *Health Ministry, it was created under the Decree* N° 1490/1992 *P.E.N* (15).

This is the entity in charge of authorizing the use of Herbal preparations in the territory of Argentina.

Regarding the use of Chinese medical substances (these are vegetal, mineral or animal substances) Argentina has two different situations. One is the difficulty in obtaining such medical substances, it is almost impossible to obtain the variety they have in their country of origin. Since 1990 China has registered 96,592 combinations of herbs which are under permanent development and investigation (16).

On the other hand, we cannot count on university training centers to teach the use of herbs and medical substances as taught in China due to the impossibility to acquire them.

As we can see, these two realities intermingle to become an impediment to a serious study of these matters.

Levels of acceptance

In other countries, there are clear and specific rules and laws to regulate the exercise of the so called integrative and complementary medicines. There, the government has a holistic approach to health services and implements public politics to integrate these practices to public and private health attention. It is our responsibility to work and fulfill the commitment Argentina has acquired with the WHO. This will allow people from different economic levels to receive treatment with integrative medicines, creating equity of access. Nowadays, integrative and complementary health treatments are only available in private offices, and so it is only accessible to those who can pay for a private treatment session.

The number of people requesting for treatment by these medicines is constantly growing in our country. Argentina has a public health system, and most services are completely free. The government could obtain benefits if TCM is applied in public health institutions because prescriptions will be reduced in number and therefore the expenses incurred in the purchase of drugs will be considerably lower. To achieve this, all types of medications and treatments must be available to the majority regardless their social status.

The importance of regulating training programs must be taken into account, not only at the university, but also at postgraduate levels. In addition, these regulations are vital to achieve the objectives. Then all professionals using TCM or any integrative medicine must also be regulated by clear rules. In Argentina there is already an example in Mendoza, it is our task to spread it to the rest of the territory.

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