

The regulation of Chinese medicine in Spain

Ramon Ma Calduch Farnòs

Larache,10, 43870 Amposta (Tarragona), Spain

Correspondence to: Ramon Ma Calduch Farnòs. Larache,10, 43870 Amposta (Tarragona), Spain. Email: rmc@mtc.es.

Abstract: Acupuncture and traditional Chinese medicine have existed for thousands of years in their country of origin and area of influence. They have been gradually introduced in the West. However, it is not until the last 40 years that their implementation has achieved great notoriety. This fact has generated a controversy that ranges from its most staunch defenders to the most stubborn detractors, one based on its benefits and the other on its lack of scientific evidence. The WHO Strategy 2014-2023 on Traditional Medicine urges member countries to regulate it, as a preliminary step to its incorporation into each country's National Health System. Even so, the controversy persists, although in recent years we have seen how it was regulated in countries such as the USA, Australia, Chile, Portugal, etc., in other countries it is in the process of being regulated to a greater or lesser extent. This article is based on the research carried out by the author, during the elaboration of his doctoral thesis and, therefore, on the sources of the mentioned doctoral thesis: compilation and comparative analysis of the existing regulations; review of the existing bibliography (articles in specialized journals, presentations in congresses, studies of the sector and published qualitative and quantitative data); in a review of judgments for intrusion and of the contentious-administrative order in Spain and, finally, a review of studies indicating the use of TCM by citizens. From the analysis of the state of the matter in the different countries of the world and in Spain, we will see that there is a tendency to regulate TCM in an autonomous way, with respect to Western allopathic medicine, while the practice of the so-called "integrative Chinese medicine" (combination of Chinese and Western allopathic medicine) and the research projects on this subject are advancing.

Keywords: Chinese medicine; acupuncture; legal framework; regulation

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Introduction

Traditional medicine, and especially Chinese medicine, has an important place in the environment of developed countries and also in Spain. And while its implementation and development has often not been easy in a Western world commonly closed off and locked into the dominant system of conventional medicine, it has been occupying positions in society's medical care and the health systems that govern it.

To talk about the use of traditional medicines as a whole, and Chinese medicine and acupuncture in particular, is to talk about a reality in constant evolution, especially in recent times. The advances in the last decades have been remarkable and of great significance, but especially if something has changed during these last decades, it is the level of penetration that they have reached.

It has been years, or rather thousands of years, that traditional medicines exist, and also, thousands of years, that Chinese medicine, as one of these traditional medicines that it is, serves the health care of the patients who undergo it. But it is not so many years ago that Chinese medicine and the set of traditional medicines have reached a dimension of high depth in all areas of society and in the majority of the realities of developed countries, other than their country of origin.

The fact is that although Chinese medicine and traditional medicines as a whole "have always been there", the support and complicity needed to develop or sustain them have not always been there. And it is relatively

recent, from the current era, in which from all fronts (and increasingly so) the development of this type of alternative and complementary medicine to conventional Western medicine is being promoted and stimulated.

There is no lack of good reasons for this, and the support and social use that is made of them demonstrates this well. Today it is already very evident that a large part of society uses or wishes to use this type of medicine, that the vast majority of societies are well aware of it, and that the degree of satisfaction with traditional medicines is very high. Proof of this is also the recently published WHO Strategy 2014-2023 for Traditional and Complementary Medicines.

On the other hand, the situation of health studies (the so-called health sciences studies) is not far from the legal and administrative reality that surrounds them, but despite this, they do collide fully with the social reality that is lived. In the same way (and despite the rapprochement in recent times, and a greater predisposition to correct it) that the legislation gives an absolute focus and predominance to medicine with western roots, to allopathic medicine, to the detriment of other types of medicine, such as Chinese medicine, also the reality of the classrooms and training centres (whatever they are) is part of the official framework that perpetuates the false image of one and only valid model of medicine. This is evidenced by the so-called "integrative medicine" (combination of both medicines), which, although it is not studied at universities, is the object of research and implementation in prestigious hospital centres in different countries of the world.

To make room for training in the field of so-called traditional and complementary medicine, such as Chinese medicine, and within it, techniques such as acupuncture, we would have to go to specific centres designed solely for these purposes. Even so, we also find that not only does the system not favour interaction, interrelation and synergies between medical systems, but it even makes the functioning of these centres oriented towards those medicines, therapies and techniques that are not predominant in the West, such as, among others, the system of Chinese medicine in an individual and regulated way, difficult.

There is still another aspect to be dealt with, such as the traditional products used in treatments, the reality of which does not correspond to the regulation to which they are subject, which often makes their access difficult and even prevents them from being legally placed on the market, favouring alternative channels for their acquisition by users.

Regulation and reality of studies in acupuncture and Chinese medicine

In Spain, health studies are framed in the Spanish educational system within the branch called Health Sciences.

The Health Sciences, by definition, are the "discipline that provides adequate knowledge for the prevention of diseases and the promotion of health and well-being of both the individual and the community" (1). This definition is fully related to the definition given for example by the WHO on the term health: "Health is the perfect physical, mental and social well-being of an individual."

If we focus on the Spanish educational field, in the official training area, we will find that the different training courses in the area of Health Sciences are broken down into two circuits, the so-called Vocational Training (VT) circuit, and the university circuit, and it is in these two circuits [two independent circuits, or rather currently interdependent and interrelated as established by the official Vocational Training circuit approved by the Spanish Ministry of Education (2)], where the entire range of subjects, branches and training sub-branches related to the Health Sciences that can be officially taught, studies that will obviously lead to the corresponding approved qualifications.

Law 44/2003, of 21 November 2003, on the management of health professionals (LOPS), contains the basic regulation in relation to the professions and health professionals. Despite the fact that the LOPS refers generically to health professionals, it is important to distinguish, first of all, between qualified and regulated health professions (article 2 of the LOPS) and professionals in the field of health professional training (article 3), as well as the characteristics and training of each type.

To date, no university degree or vocational training or professional qualification has been developed in the health professional family for acupuncture, Chinese medicine or other natural therapies.

In its article 2, LOPS establishes that: "Qualified and regulated health professions are those whose pre-graduate or specialized training is specifically and fundamentally aimed at providing those concerned with the knowledge, skills and attitudes proper to health care, and which are organized in professional bodies officially recognized by the public authorities, in accordance with the provisions of specifically applicable regulations."

The functions of these professionals are developed in Articles 6 and 7 of the LOPS, which establishes the functions of each of the health professions, and the various specific characteristics of these professions, for the exercise of which it is required to hold the corresponding degree.

Apart from the professions listed in the LOPS, article 2 states that: "When it is necessary, due to the characteristics of the activity, to improve the efficiency of the health services or to adapt the preventive or assistance structure to scientific and technological progress, the character of a certain activity not provided for in the previous section may be formally declared as a health profession, qualified and regulated, by means of a rule with the rank of law." This refers to activities previously not included in the health professions (neither those enabled by a degree or diploma, nor those qualified by a specialist title in the health sciences).

Finally, in the training of professionals, the LOPS provides for the possibility of the health authorities issuing certificates of accreditation and advanced accreditation.

With regard to professional training, Article 10.1 of Organic Law 5/2002 states that the General State Administration will determine the professional titles and certificates, which will constitute the offers of professional training related to the national catalogue of professional qualifications.

University education in Spain is regulated by Law 4/2007, of 22 April, on the structuring of university education and qualifications, which modifies Organic Law 6/2001, of 21 December, on Universities. It is implemented by Royal Decree 1393/2007, of 29 October, which, in turn, has been modified by Royal Decree 861/2010, of 2 July, which establishes the organization of official university education.

Universities offer bachelor's, master's and doctoral degrees in education, leading to the corresponding official qualifications. Regulated university degrees that are official in nature and valid throughout the national territory, with full academic effects and which allow regulated professional activities to be carried out, in accordance with the regulations derived from the application in each case.

What was said in the immediately preceding lines is noteworthy, as it allows us to begin to enter into and comment on the reality of health studies in the official Spanish educational framework. We will see that decentralisation, which in other countries provides a wealth of opportunities, does not apply to health matters in Spain. We can clearly see this in the impediments that, for example, some autonomous governments have had and still have, such as the Catalan government, which in its eagerness to take a step forward and regulate practices related to traditional and complementary medicines (3)

has tried to regulate them, finding itself with multiple controversies that have managed to annul the creation of a current, complete and effective framework in this respect.

It is precisely in this lack of adaptation to the new medical and social realities that we find one of the reasons why the educational system cannot and does not know how to give a clear and effective response to all the needs and realities demanded by society today.

As far as Chinese medicine and acupuncture studies are concerned, the Spanish Ministry of Education and Science considers Chinese medicine and acupuncture studies as non-regulated education and, as such, they are not officially recognized.

Training in acupuncture and Chinese medicine is provided in many different institutions (universities, private schools, professional colleges, associations, etc.) and is aimed at both health professionals and non-health professionals.

In conclusion, on the one hand there are health professionals who may have received training in acupuncture and/or Chinese medicine, and on the other hand there are non-health professionals who have acquired their knowledge through private schools, such as non-regulated education, or at universities, with a master's or post-graduate degree, if they have a university qualification in any area, or a certificate of achievement in acupuncture/ Chinese medicine, if not.

In short, a vital point for the Spanish educational system to be fully efficient and gain in quality, competitiveness and to see its objectives fulfilled, is that it should give a more real and adequate response to what society and the labour market demands.

To mention this last point, as far as acupuncture and traditional Chinese medicine are concerned, it is obvious that the Spanish educational system is on a path, with certain curricula and degrees (and aimed at certain health professionals), and a good part of the medical and health market, the labour market and the social market, look precisely, in an important way, to the other side.

To conclude, it should be said that, although the general reality of the Spanish educational system is as described above, initiatives such as those carried out by different Spanish universities to create their own studies (masters, university experts, etc.) in different areas of knowledge and also for those directly related to traditional Chinese medicine and its techniques, should be also highlighted and celebrated.

In conclusion, with respect to the possible locations of studies in Chinese medicine and its respective techniques such as acupuncture, in the Spanish Educational System, we would like to indicate that, in our opinion, the only appropriate location for these studies is that which allows them to train and develop specific graduates in the subjects they teach, without having to have a direct relationship with conventional health professionals. In other words, students of Chinese medicine and acupuncture can study and become practitioners of these medicines directly and be officially recognized as health professionals, without having to previously qualify as Western doctors or health graduates.

It should also be pointed out that the two existing circuits in health sciences in the Spanish educational system are already optimal and adequate for making the studies of Traditional, Complementary and Integrative Medicine official, that is, it is not necessary to change the system or the existing mechanisms, it is simply necessary to include these disciplines as disciplines in their own right within university studies and within non-university studies, in the branch of Health Sciences, not as appendices or complements to the existing ones of an allopathic nature. This is on the understanding that, for acupuncture and traditional Chinese medicine, such studies should be confined to the field of higher and/or university studies.

Regulation and reality of the professional practice of acupuncture and Chinese medicine

In Spain, unlike other countries and our neighbouring country, Portugal, there is no regulation for the practice of natural therapies and therefore neither of Acupuncture and TCM.

In fact, after the report issued in December 2011 on natural therapies by the Commission in charge of it, within the Health Commission of the Spanish Parliament, we have not observed any major movements of regulatory interest, except for a report from the Commission of Non-Conventional Medicines of the Spanish Medical Association. And this is despite the insistence of the professional associations.

In recent years we have been witnessing a kind of persecution against natural therapies in the sense of accusing them of a lack of scientific evidence and advocating the prohibition of their practice. Also, during the past year 2019 an intense campaign was carried out against the so-called pseudosciences, due to "the danger that their lack of scientific evidence represents to the citizens", including acupuncture and traditional Chinese medicine, by the Minister of Health and Consumer Affairs and the Minister

of Science and Universities.

Evidently, the lack of regulation of natural therapies in Spain allows good professionals and charlatans to be confused, harming the former and the citizens in general.

There is already a Commission on this subject (for the regulation of the different natural therapies) within the Health Commission of the Congress of Deputies which, at the time, began its work and which is currently completely stopped. The aim is to promote this Commission and, finally, to approve the regulation that is being sought and demanded by all.

At the level of autonomous communities, Catalonia was the only one in which a specific rule was drawn up to regulate these therapies, which was later annulled by the TSJC and the Supreme Court. Catalan Decree 31/2007 was a laudable attempt, which was annulled by the judgments of the Catalan High Court of Justice and the Supreme Court, because it is Basic State Legislation, the exclusive competence of the State, and not for other reasons.

The case of Spain is typical of a country where medical and health practices are officially reserved solely and exclusively for specialists in conventional Western medicine, without giving the other systems a chance to enter this conventional system. This limitation does not only affect Chinese medicine and not even the set of alternative and complementary medicines. On the contrary, this limitation affects the Western system itself (and with it, society in general) which limits itself and renounces the synergies and advantages that an interaction with alternative and complementary medicines, and specifically with the techniques, systems and procedures that Chinese medicine would bring to it.

To date, there is no regulation in Spain regarding acupuncture and Chinese medicine, beyond what is regulated by Decree 1277/2003, for health professionals, the heading for fiscal discharge and the sector's labor agreement for non-health professionals (paramedical services) who practice them. There is also no specific regulation on the training or certification of persons who practice acupuncture and Chinese medicine. In fact, health professionals and non-health professionals who practice them coexist.

For health professionals, decree 1277/2003 establishes, in its classification of health centres, the U101 health care unit (non-conventional therapies), which requires the director of the centre to be a Western doctor. As a result, health professionals who are not physicians must practice acupuncture and Chinese medicine as paramedics or be under the direction of a Western physician.

For those who are not health professionals, the regional health authorities (which are the ones with the powers of inspection) are aware that there are centres that are not registered as health facilities, legally established, due to "the lack of regulations governing this specific health care".

Non-healthcare professionals of acupuncture and Chinese medicine are registered with in the corresponding social security scheme and obtain the registration of economic activity, as well as the municipal licence as paramedical professionals related to paramedical activities (naturopaths, acupuncturists and other paramedical professionals), under the protection of Royal Decree 1175/1990, of 28 September, approving the tariffs and instructions of the tax on economic activities, which includes in its annex 1 such economic activity in group 944: services of naturopathy, acupuncture and other paramedical services, and as a professional activity in group 84: professionals related to paramedical activities, of group 841: naturopaths, acupuncturists and other paramedical professionals.

Likewise, it is established (in several judgements of the Supreme Court and several Provincial Courts) that the practice of acupuncture and Chinese medicine cannot be considered an offence of intrusion, when it is carried out by non-health professionals, because of the lack of proof that these are "own acts".

On the other hand, although some private insurance companies include them in their coverage, acupuncture and Chinese medicine are not financed by the public health system. However, in the case of acupuncture, there are several acupuncture units in public hospitals and primary care centres.

There is a high number (much higher than the number of health centres) of acupuncture and Chinese medicine centres in Spain, without health authorisation, where nonhealthcare professionals are practising, registering as nonhealthcare centres and avoiding advertising with medical terminology.

The legal vacuum, or more properly the uncertainty, is evident, being that in the reality of our country and others where regulation is lacking, it turns out that there are more non-health professionals with open centres, than health professionals who practice acupuncture and traditional Chinese medicine.

It should be noted that there are no criminal lawsuits against non-health professionals for the exercise of their activity. This is due to the fact that if the professional can accredit the necessary knowledge (via degree and academic program) for the activity he or she is carrying out, the ruling will be favorable to him or her, as the studies are not

regulated, there is no reservation of degree in favor of any health profession.

In the case of acupuncture and Chinese medicine, to a greater extent than what we have referred to above, we must state clearly that the professionals who provide their services in this area cannot currently be included, in Spain, as health professionals (unless they are health professionals who practice acupuncture/TCM), for the simple reason that at present there are no regulations that directly or indirectly can regulate or affect in any way the existing controversy. It should be pointed out that the professional who provides his services in a Chinese medicine establishment has a degree in traditional Chinese medicine which is, of course, one of the unofficial qualifications for non-regulated education.

The title of Acupuncture/Traditional Chinese Medicine does not correspond to a health profession, for the simple reason that it is not listed as such in the applicable regulations.

It should also be noted that there is a State Collective Labour Agreement (4) for the sector, which only highlights the lack of regulation, but also that there is a large number of non-healthcare professionals, which justifies this Collective Agreement.

The approval of this collective agreement, beyond its transcendence as a framework for regulating working conditions, implies the recognition for social and labour purposes of a sector of activity that is characterised by the absence of legal and regulatory regulation in Spain.

Regulation and reality of Chinese phytotherapy

The use of medicinal plants is regulated in Spain by Law 29/2006, of 26 July, on guarantees and rational use of medicines and health products (modified by Law 28/2009, of 30 December), and by Royal Decree 1345/2007 of 11 October, which regulates the procedure for the authorisation, registration and dispensing of industrially manufactured medicines for human use.

Article 51 provides that the Ministry of Health and Consumer Affairs (currently the Ministry of Health, Social Services and Equality) shall establish a list of plants whose sale to the public shall be restricted or prohibited due to their toxicity, and that there are plants that may be freely sold to the public, as they are traditionally considered to be medicinal plants, provided that they are offered without reference to therapeutic, diagnostic or preventive properties, and that their itinerant trade is prohibited.

Royal Decree 1345/2007, in its fourth section, is dedicated to traditional herbal medicines.

On the one hand, this Royal Decree establishes the obligation to register traditional herbal medicinal products. It sets the criteria to be met for registration using the simplified procedure, the grounds for refusal of registration and withdrawal from the market when an herbal substance, preparation or combination of herbs is no longer included in the list drawn up by the Committee for Herbal Medicinal Products of the European Medicines Agency.

In addition, Order SCO/190/2004 of January 28th draws up a list of plants whose sale to the public is prohibited or restricted because of their toxicity.

On the other hand, it should be remembered that if the application of a technique requires a medical device, it must comply with the provisions of Royal Decree 1591/2009, of 16 October, which regulates medical devices.

In view of the disparity of regulations on herbal products in the different EU countries, in April 2004 Community Directive 24/2004/EC was published on "traditional herbal medicines", which allowed for simplified registration, and this was gradually transposed into the legislation of the EU Member States, including Spain.

In countries like Spain, this Directive 24/2004/ EC, transposed in Spain by RD 1345/2007, has not really affected the previous situation. In fact, Chinese phytotherapy was (and is) considered a medicine by the Spanish Agency for Medicines and Health Products (AEMPS). Therefore, we have not gone worse: before, Chinese phytotherapy was forbidden, if it was not registered as a medicine (the health authorities do not admit that it is a food supplement), and now it is still forbidden. Even so, the Community Directive introduces the concept of mutual recognition, which benefits us, since when these products are registered in any EU country, Spain (or any other EU country) cannot oppose the registration, unless it proves that it has a certain degree of danger.

We should also mention here that, in health matters, there is a principle at EU level called legal reserve, which means that a country is not obliged to admit medical products that are legal in another EU country or to apply the same criteria when they are possibly marketed. This is why, even if a product is legal in one EU country, it cannot be marketed in another, if its regulation does not admit it. This does not prevent a citizen of any EU country from buying such products for his own use in the country where they are freely marketed, in the interests of the free movement of goods. The only exception to this principle is mutual recognition, which has not been used up to now but is now becoming very popular.

In addition, it should be noted that work is underway to prepare a series of monographs on Chinese herbal medicine formulas. This is in order to be able to register products in the EU as traditional herbal medicines.

Personally, I believe that we must seek for an independent solution for Chinese phytotherapy at European level, given its own characteristics. In the meantime, in order to avoid a lack of products for patients, the route of food supplements and monographs for registration as traditional herbal medicines could be a transitional solution that would allow the placing on the market, by means of mutual recognition, of those countries that are less permissive, such as Spain.

Finally, it should be pointed out that Chinese phytotherapy is currently available in Spain, marketed by laboratories that have registered the products as food supplements in Belgium or other EU countries and that have been communicated in Spain through mutual recognition. In addition to the purchase by internet that can be made directly by patients in other EU countries, in the interest of the free circulation of products.

Level of acceptance by the population

Nothing better than to start this section with some data that show the excellent reception, and especially the excellent satisfaction that also in the Spanish public generate the treatments based on the natural therapies. Specifically, it is interesting to start with the data provided by a report (5) prepared by the General Council of Physiotherapists' Associations of Spain, a report which mentions, for private treatment with cost to the patient, of chronic back pain and cervical pain, with a population of 268 patients treated, of which 33% showed an improvement in functional capacity and 11% in psychological well-being. Patients showed excellent satisfaction with the care received [...].

In May 2008 a study was published by the so-called Observatory of Natural Therapies (under the sponsorship of the COFENAT, CONAMAD and TENACAT societies). The quantitative study is based on an interview with a sample of 2,000 individuals, [...]. It highlights that 95.4% of the Spanish population knows of some natural therapy, the most popular being: yoga, acupuncture/traditional Chinese medicine, tai-chi, chiropractic and homeopathy, all of which are mentioned by more than 50% of the population. 23.6% of the population has at some time used natural therapies, mainly yoga, acupuncture and chiromassage.

In this same order of things, the same report highlights that the frequency of use of each of the branches of natural therapies, by the total of the population that undergoes natural therapies is the following: yoga: 32.5%, acupuncture/Chinese medicine: 31.5%, chiropractic: 28.4%, homeopathy: 23%, foot reflexology: 16.1%, tai-chi: 13.3%, flower therapy: 12%, lymphatic drainage: 9.1%, naturopathy: 8.8%, reiki: 8.4%, osteopathy: 8.2%, shiatsu: 3.9%, kinesiology: 2.1% (6).

To finish with this study, it should also be noted that, according to it, the majority profile of use among the Spanish population, responds to the following portrait:

- Higher percentage of female than male users;
- Predominance of upper-middle/high class users;
- Age mostly between 36 and 45, and;
- Users mainly resident in urban metropolitan áreas (7).

In this same order of things, but in this case emanating from the study (8) that the Department of Health of the Generalitat de Catalunya elaborated, with respect to the Spanish case, the data that the same one threw are interesting, in this case estimating that 67% of the chronic patients use some type of natural therapy.

In this respect, the results offered by a study developed by TENACAT (9) are also very outstanding. A study which, dealing with the use and satisfaction of natural therapies in Spain, provided the following data:

- 44% of the interviewees, the object of the study, mentioned one or more natural therapies spontaneously.
- The ranking of spontaneous knowledge is led by acupuncture, yoga and homeopathy.
- 96% of the interviewees recognized one or more natural therapies in a suggested way.
- The ranking of suggested knowledge is led by yoga, followed by acupuncture, tai chi, chiropractic massage, homeopathy and naturopathy.
- 24% of the interviewees admitted having received a natural treatment at some time.
- ❖ The degree of satisfaction (with the use of natural therapies) by those interviewed reached 60%. Sixty percent were "very or fairly satisfied" with the question posed.

In view of this, it is time to situate ourselves specifically in the field of herbal medicines, within natural therapies as a whole.

And it is interesting to stop in this branch, because for example according to data from EFE (10), 20% are regular users of this type of medicine, which demonstrates the power of these types of solutions.

In this respect, the data provided by Diego José Martínez

Martín (11) is also interesting. During a round table discussion, he commented on the year-on-year growth of herbal medicines in Spain in 2000, which, according to Martínez, had already reached "30%".

The data on herbal medicines is complemented by data from the Therapeutic Information Bulletin (12) dated 2003 and produced by the Department of Health of the Generalitat de Catalunya, which, focusing on the Catalan area, highlighted that nearly 50% of the Catalan population habitually consumes medicinal plants, and that the consumer is between 40 and 64 years of age, although consumption among those under 25 years of age is growing. A very interesting fact is that 42.9% of chronic patients consume medicinal plants, in addition to their usual medication for the same pathology, despite the fact that, in general, medicinal plants purchased in pharmacies are used especially, to treat mild digestive problems, nervous problems and excess weight.

According to a study carried out by the DYM Institute, on the use and consumption habits of Natural Therapies in Spain, dynamism has been the prevailing trend in the field of natural therapies in recent years. The progressive implementation of some natural therapies (among which acupuncture and TCM are included), in a complementary way to Western medicine, allows us to affirm that there is a change in the way of understanding the care of one's own health.

The concept of Natural Therapies currently presents a beneficial global image, both with respect to the emotional and physical aspects, for all the segments analysed.

According to the 2016 FECYT (Spanish Foundation of Science and Technology) survey, 59.8% believe in the therapeutic utility of acupuncture and 52.7% consider homeopathic products to be effective.

Finally, it should be noted that the CIS (Centro de Investigaciones Sociológicas) Barometer of February 2018 shows that 6.2% of Spaniards went to an acupuncture professional and up to 9.8% to a homeopath.

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