

Traditional Chinese Medicine and Medical Liability: Regulatory and Judicial Developments and Future Prospects

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ABSTRACT: The growing popularity of Traditional Chinese Medicine (TCM) in Italy raises important medical-legal and ethical issues. Although increasingly present in hospitals, universities and in the management of chronic diseases, TCM is not recognised as an autonomous discipline: it is classified as an unconventional practice reserved for doctors. The absence of specific legislation creates uncertainty regarding informed consent, standards of care and professional responsibility. The article also analyses recent case law and ethical principles, highlighting the need for a clearer regulatory framework, accurate documentation, interdisciplinary communication and continuous training to ensure safety and professional protection.

KEYWORDS: Acupuncture; medical act; medical liability; traditional Chinese medicine; legislation

SUMMARY: 1. Background – 2. Unconventional Medicine – 3. Material and Method – 4. Results – 5. Discussion – 6. Conclusions.

1. Background

In our system, there are no provisions stipulating what medical activities are, but a medical act is what is taught as such in universities.

Article 100 of R. D. July 27, 1934 no. 1265 (Unified text of Health Laws) provides that “no one may practice as a medical surgeon [...] unless he or she is of legal age and has obtained a professional qualification in accordance with the regulations in force”.

Professional licensure, acquired by passing a state examination,¹ presupposes a medical degree. It should also be taken into account that, according to the legislative decree of the Provisional Head of State that established the Orders of Surgeons, Veterinarians, Pharmacists and Colleges of Midwives,²

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¹ Art. 33, co 5, Italian Constitution.

² Legislative Decree PCS no. 233 of September 13, 1946.

registration in the professional register³ is necessary for the practice of the health profession and that one of the requirements to be registered is to have “obtained an academic degree given or confirmed by a university or other institution of higher learning”.⁴

So, the Medical Act is recognized in an indirect way by the Ordinance: those disciplines covered in university teaching are medical. Consider now that the Unified Law on Higher Education⁵, with Article 1, states: “The purpose of higher education is to promote the progress of science and to provide the scientific culture necessary for the exercise of offices and professions”.

The scientific model in our tradition is the Galilean experimental model. Therefore, the medical activity to which the law indirectly refers is scientific because it is the subject of university teaching⁶.

2. Unconventional Medicine

Healing practices that do not belong to evidence-based medicine and that the European Parliament in a resolution of May 1997 called unconventional medicine are assuming great importance.

In some EU countries, non-conventional medicines have been specifically regulated.

In Italy, the medical activity to which the law makes indirect reference is conventional and scientific medicine, because the only one that is the subject of university teaching. From this it follows that, according to the legislative system, in the past, non-conventional medicine could not have been included in the definition of a medical act and as such, not constituting a medical activity, could have been practised by anyone without incurring the offence of abusive exercise of the profession, provided for and punished by Article 348 of the criminal code. This logical conclusion was also highlighted by judicial decisions.

In 1981, the Court of Perugia stated⁷ that

the health profession is that which includes the diagnostic-curative activities forming part of the current order of studies in medicine. The activities carried out by ‘Healers’ are not taught by universities nor subject to examination in State examinations and since they do not form part of the medical profession, their exercise does not constitute abusive professional practice[...].

The same principle was reiterated for Chiropractic.

According to the Constitutional Court,⁸ Article 348 of the Criminal Code only punishes anyone who abusively exercises a profession for which a special State authorisation is required. Since the Italian legal system does not require any authorisation for the profession of ‘chiropractor’, which our law ignores,

³ Art. 8 L.D. CPS 233/46.

⁴ Art. 9 D. I. vo CPS 233/46.

⁵ The text in question was approved by Royal Decree 1592 of August 31, 1933.

⁶ S. RICCI, A. MIGLINO, *Atto Medico e Consenso Informato*, 2009; F. MASSONI, C. SIMEONE, E. LUZI, C. PALLA, S. RICCI, *Appropriateness prescribing and doctor’s professional responsibility*, in *La Clinica Terapeutica*, 163, 4, 2012, 193–99; F.M. DAMATO, P. RICCI, R. RINALDI, *Informed consent and compulsory treatment on individuals with severe eating disorders: a bio-ethical and juridical problem*, in *Clinica Terapeutica*, 174, 4, 2023, 365–69; K. CHAN, *The Evolutional Development of Traditional Chinese Medicine (TCM) Outside the Chinese Mainland. Challenges, Training, Practice, in Research, and Future Development*. *World Journal of Traditional Chinese Medicine*, 2, 4, 2016, 6–28.

⁷ COURT OF PERUGIA, Italy, 16 February 1981, (see on acupuncture) in *Riv It Med leg*, 1981, 847.

⁸ CONSTITUTIONAL COURT, 2 February 1988, no. 149, in *Giust Cost*, 1988; 1, 489.



until such time as the State decides to regulate it and require a special authorisation for its exercise, it will remain a professional occupation protected by Article 35, paragraph 1, of the Italian Constitution, in all its forms and applications, and a free private initiative referred to in Article 41 of the Italian Constitution, with Article 348 of the criminal code being absolutely inapplicable.⁹

This jurisprudential conception, which was absolutely adherent to the letter of the law, has been overtaken by case law in the course of time, which has sought to better protect the health of citizens.

For Acupuncture, in Italy, the Supreme Court, in a ruling of 6 April 1982,¹⁰ held that

a medical degree is required for the practice of acupuncture: anyone practising acupuncture who lacks such a qualification commits the offence set out in Article 348 of the Criminal Code aimed at protecting public health. In fact, although acupuncture does not constitute a subject of teaching in Italian universities, it can only be practised by doctors or surgeons, knowledge of medicine or surgery being necessary to make an exact diagnosis and to avoid harmful consequences for the patient.

For the S.C., therefore, “acupuncture falls within the broader category of the profession”.

The jurisprudence on the merits has conformed to this guideline.

According to the court of Gela,¹¹ since all acts aimed at diagnosing illnesses and prescribing remedies to treat them (even if different from those ordinarily practised) are typical acts of a doctor, the practice of Iridology (the case at issue in the decision), since it is aimed at making a diagnosis and prescribing a therapy (even if it is based on natural methods), is the performance of a health profession and, as such, subject to the prescribed State authorisation.

It follows from this that those practising Iridology commit the crime of abusive exercise of the medical profession, since they perform acts that are typical and exclusive to a doctor, such as examining patients, diagnosing an illness and prescribing a cure, without holding a medical degree.

The Turin Magistrate’s Court¹² assumes that healthcare activity is that which takes place in the diagnosis of an organic alteration or a functional disorder of both body and mind, in the identification of the necessary remedies and in the administration of remedies of the same, carried out directly by the doctor or, possibly, by means of paramedics under the control of the healthcare professional. Therefore, both Pranotherapy, Hypnotic Induction and Acupuncture are therapeutic techniques whose exercise requires a licence to practise as a doctor, without which one incurs the offence referred to in Article 348 of the Criminal Code.

And again: the Civil Cassation¹³ ruled that “integrates the crime of abusive exercise of the medical profession under Article 348 of the Criminal Code the conduct of those who make diagnoses and issue prescriptions and health prescriptions for homeopathic products. Such activities are in fact part of the exercise of a health activity that presupposes – for legitimate performance – the possession of a valid and suitable title”.

⁹ CRIMINAL CASSATION, Italy, sez. VI, 4 April 2005 no. 12626, in *Rass Dir Farmaceutico*, 2005; 6, 1213.

¹⁰ K. CHAN, H. LEE, I. CHAPTER, *The Historical Evolution of Chinese Medicine and Orthodox Medicine in China*, in *The Way Forward for Chinese Medicine*, 2002; 1–21.

¹¹ PRETURA OF GELA, Italy, 16 January 1995, in *Cass Pen*, 1995, 1663 and in *Giur Merito*, 1995, 509.

¹² PRETURA OF TORINO, Italy, 19 January 1983, Coccolo, in *Riv It Med leg*, 1984, 221.

¹³ ITALIAN COURT CASSATION, 6th civil section, 25 February 1999, no. 2652, in *Rass Dir Farmaceutico*, 1999; 479.

As we can see, jurisprudence, motivated by the aim of protecting the health of the citizen regarding those who do not possess adequate clinical knowledge, has taken a different path from that indicated by the law, including in medical activity practices that, although not the subject of higher education, involve therapeutic functions.

In Italy, the legal status of non-conventional medicines in the mid-1990s was ambiguous.

On one hand, there were regulatory provisions from which it appeared that our system excluded non-conventional medicines because they were not included in the curricula of university studies; on the other hand, there was case law that attributed the nature of a medical act to certain practices in the medical field that are not included in such curricula.

It may well be said, then, that an unconventional practice is legally considered a medical act when it is the subject of university teaching or jurisprudential decisions qualifying it as such.

This second eventuality is, however, absolutely problematic.

In most cases, judges deal with the issue from the point of view of the abusive exercise of the medical profession and make their determinations from time to time. There can therefore be different and even contradictory positions and, until the Supreme Court of Cassation rules (a body at the top of the judicial organisation, whose task is, *inter alia*, to ensure the exact observance and uniform interpretation of the law), one cannot be certain whether a discipline is to be definitively considered medical (Only in the case of acupuncture and homeopathy has the Supreme Court ruled).

Moreover, the Supreme Court's own guidelines may change.

Ours is a system that we could define as 'dynamic', precisely to indicate, without thereby expressing any value judgement, that the legal status of non-conventional medicine is not unitary: only practices that are taken into consideration by the academic or jurisprudential world can rise to the legal dignity of a medical act.¹⁴

The practice of Traditional Chinese Medicine (TCM) has deep roots in history and has influenced the health and well-being of millions of people worldwide. The basic knowledge of TCM mainly includes the theories of yin-yang, the five elements, zang-fu, 'Qi', blood and body fluid, meridians and collaterals. The main TCM techniques include acupuncture, moxibustion, herbal medicine, tuina, diet and Qigong. Diagnosis in TCM is based on a detailed analysis of the patient's symptoms, physical appearance, pulse and tongue. Once the underlying causes of the disease have been identified, treatment aims to restore the individual patient's energy balance.

The fundamental principles that the physician must respect while exercising his profession are well defined by legal and deontological norms and the main aspects to be respected fall under the terms of prudence, expertise and diligence.

The same fundamentals of professional liability relating to imprudence, inexperience and negligence and non-compliance with laws and regulations apply to the acupuncture doctor.

The contract of care between physician and patient justifies the physician's act, which hinges on two essential foundations: informed consent and the provision of medical care, both of which are part of the required conduct.¹⁵

¹⁴ ISTITUTO PARACELSO, *Elementi essenziali di agopuntura cinese*, Roma; 2002, 2^a ed.

¹⁵ S. RICCI, *et al.*, *op. cit.*; F.M. DAMATO, P. RICCI, R. RINALDI, *op. cit.*



From the point of view of forensic medicine, the medical act is a complex act involving several intersecting steps: prevention, diagnosis, treatment, rehabilitation, certification. The fundamental element is that it is not possible to practise a treatment without first making a diagnosis, an activity only possible by a doctor¹⁶.

Acupuncture cannot be practised without a diagnostic indication, which is exclusively a medical act and therefore acupuncture is a medical act.¹⁷

Acupuncture, like other therapies such as homeopathy, homotoxicology, phytotherapy and other homologous therapies, is counted among the unconventional therapies, which require specific knowledge of medical science and which carry out a health activity consisting, that is, in a diagnosis of an organic alteration or functional disorder of the body or mind and in the identification of remedies and their administration by a physician or paramedical staff under medical supervision.

To date, TCM is the subject of growing interest and integration, giving rise to crucial reflections on the medical responsibility associated with a therapeutic system so different from Western paradigms.

A significant turning point for non-conventional medicine is the approval of the new Essential Levels of Care (LEA), completed with the decree published in the Italian Official Gazette on 23 June 2023.

3. Material and Method

The main documents that have considered Non-Conventional Medicines, from the inception of the issue to the present day, were analysed.

Reference was made to the indications derived from the scientific literature for the use of acupuncture and other TCM techniques.¹⁸ The guidelines¹⁹ of the main national and international health protection

¹⁶ P. RICCI, F. MASSONI, L. RICCI, E. ONOFRI, G. DONATO, S. RICCI, Quality of life in dementia sufferers: The Role of Diet and Exercise, in *Current Alzheimer Research*, 15, 5, 2018, 400–07; T. ARCHER, S. RICCI, F. MASSONI, L. RICCI, M. RAPP-RICCIARDI, Cognitive benefits of exercise intervention, in *Clinica Terapeutica*, 167, 6, 2016, 180–85.

¹⁷ F. MASSONI, et al., *op. cit.*; ITALIAN COURT OF CASSATION, 6th Criminal Section, maxima of 27 March 2002 no. 482.

¹⁸ K. CHAN, The Evolutional Development of Traditional Chinese Medicine (TCM) Outside China Mainland: Challenges, Training, Practice, Research, and Future Development, in *World J Tradit Chin Med*, 2, 4, 6–28; K. CHAN, X. HU, V. RAZMOVSKI-NAUMOVSKI, N. ROBINSON, Challenges and opportunities of integrating traditional Chinese medicine into mainstream medicine: A review of the current situation, in *European Journal of integrative medicine*, 7, 1, 2015, 67–75; M.V. ROSATI, C. SACCO, A. MASTRANTONIO, G. GIAMMICHELE, G. BUONPRISCO, P. RICCI, G.F. TOMEI, F. TOMEI, S. RICCI, *Prevalenza della patologia venosa cronica negli operatori sanitari e ruolo della stazione eretta*, 38, 3, 2019, 201–10; M.S. WU, K.H. CHEN, I.F. CHEN, S.K. HUANG, P.C. TZENG, M.L. YEH, F.P. LEE, J.G. LIN, C. CHEN, *The Efficacy of Acupuncture in Post-Operative Pain Management: A Systematic Review and Meta-Analysis*, in *PLoS One*, 11, 3, 2016, e0150367; M.V. ROSATI, A. SANCINI, F. TOMEI, C. SACCO, V. TRAVERSINI, A. DE VITA, D.P. DE CESARE, G. GIAMMICHELE, F. DE MARCO, F. PAGLIARA, F. MASSONI, L. RICCI, G. TOMEI, S. RICCI, *Correlation between benzene and testosterone in workers exposed to urban pollution*, in *Clinica terapeutica*, 168, 6, 2017, e380–e387; S.A. KIM, S.H. LEE, J.H. KIM, M. VAN DEN NOORT, P. BOSCH, T. WON, S. YEO, S. LIM, *Efficacy of Acupuncture for Insomnia: A Systematic Review and Meta-Analysis*, in *Am J Chin Med*, 49, 5, 2021, 1135–1150; A. SANCINI, S. RICCI, F. TOMEI, M.V. ROSATI, C. SACCO, A. PACCHIAROTTI, N. NARDONE, P. RICCI, A. SUPPI, D.P. DE CESARE, V. ANZELMO, R. GIUBILATI, B. PIMPINELLA, *Work related stress and blood glucose levels*, in *Annali di Igiene Medicina Preventiva e di Comunità*, 29, 2, 2017, 123–33; T. LI, Y. ZHANG, Q. CHENG, M. HOU, X. ZHENG, Q. ZHENG, L. LI, *Quantitative study on the efficacy of acupuncture in the treatment of menopausal hot flashes and its comparison with nonhormonal drugs*, in *Menopause*, 28, 5, 2021, 564–72; M. JIANG, C. LU, C. ZHANG, J. YANG, Y. TAN, A. LU, K. CHAN, *Syndrome differentiation in modern research of traditional Chinese medicine*, in *Journal of Ethnopharmacology*, 140, 3, 2012, 634–42; R. FERRARA, R. NAPPO, F. ANSERMET, P. RICCI, F. MASSONI, G. CARBONE, A. SPARACI,

bodies were studied in depth, integrated with the laws of the Italian State and the decisions of the Court of Cassation. In addition, the codes of ethics in the succession of years, the Federation of Medical Orders and the decrees relating to LEAs were analysed.

4. Results

One of the first indications of the regulation of Traditional Chinese Medicine (TCM) in Europe came with Resolution No. 75 of the European Parliament of 29 May 1997,²⁰ on the Status of Non-Conventional Medicines and Resolution No. 1206 of the Council of Europe of 4 November 1999²¹ in which the member states were invited to address the problems associated with the use of Non-Conventional Medicines (NCMs).

In 1999, the World Health Organisation (WHO)²² published the Guidelines on Basic Training and Health Care Safety in Acupuncture. These guidelines presented what professional experts and healthcare regulators considered to be appropriate training programmes for acupuncture practitioners, as well as for physicians and primary healthcare personnel wishing to provide acupuncture treatment.

In the Italian FNOMCeO (Federazione Nazionale Ordini Medici Chirurghi e Odontoiatri – National Federation of Surgeons and Dentists) Guidelines on Non-Conventional Medicines and Practices (Terni, 18 May 2002), Acupuncture, together with other Non-Conventional Medicines, was recognised as falling within the exclusive competence and professional responsibility of the surgeon and dentist since it was ‘to all intents and purposes a medical act’. The document recognised nine non-conventional medicines: Acupuncture, Traditional Chinese Medicine, Ayurvedic Medicine, Homeopathic Medicine, Anthroposophical Medicine, Homotoxicology, Phytotherapy, Chiropractic and Osteopathy.

In “The Consensus Conference on Non-Conventional Medicines in Italy, Special Session of the 43rd National Congress of the Italian Society of Psychiatry, Bologna, 20 October 2003 (published in ‘La Professione’, organ of the FNOMCeO)” the following is reported “The Italian Republic protects health as a fundamental right of the individual, safeguards the principle of scientific pluralism and guarantees the citizen’s freedom of therapeutic choice and the professional qualification of health workers, enhancing in particular the physician’s autonomy in therapeutic choices”.²³

E. NONNIS, L. RICCI, S. RICCI, *The impact of dsm-5 on the diagnosis of autism spectrum disorder*, in *Psychiatric Annals*, 51, 1, 2021, 38–46.

¹⁹ G. BODEKER, C.K. ONG, C. GRUNDY, G. BURFORD, K. SHEIN, *WHO Global Atlas of Traditional, Complementary and Alternative Medicine*, in *Kobe WHO Publications*, 118, 11, 2005, 947; A. MIGLINO, L. RICCI, S. RICCI, *Liability in the medical profession*, in *Panminerva medica*, 56, 1, 2014, 127–56; F. MASSONI, P. RICCI, P. CRUSCO, L. RICCI, S. RICCI, *Applicability of the guidelines for the evaluation of the professional responsibility of the physicians*, in *Policlinico – Sezione medica*, 120, 1, 2014, 37–42; F. MASSONI, P. RICCI, E. ONOFRI, L. RICCI, E. LUZI, S. RICCI, *Evidence Based Medicine between guidelines and conflict of interest*, in *Panminerva medica*, 56, 1, 2014, 89–94; A. MIGLINO, L. RICCI, S. RICCI, *The right to health as a liberty of self-determination*, 56, 1, 2014, 13–24.

²⁰ EUROPEAN PARLIAMENT, Resolution no. 75 of 29 May 1997.

²¹ COUNCIL OF EUROPE, Resolution no. 1206 of 4 November 1999.

²² WORLD HEALTH ORGANIZATION, *Guidelines on Basic training and Safety in Acupuncture*, 1999, <https://iris.who.int/handle/10665/66007>.

²³ ITALIAN COURT OF CASSATION, 4th Criminal Section, Judgment no. 2865 of 8 February 2001.



The right to choose, acknowledged to each person as the focal point of any modern consideration of respect for the individual's will with regard to his or her state of health and illness, has already been implicitly expressed and materialised with the recourse, by increasingly broad strata of the population, to certain disciplines and therapeutic practices not under the overall term of 'Non-Conventional Medicines (NCMs)'.

The World Health Organisation, with WHO Resolution 56.31 of 28 May 2003,²⁴ then prompted the Member States to formulate and implement national policies and regulations in the field of unconventional medicine, with particular attention to staff training. In particular, the need to have certified training and to be enrolled in a specific register with one's professional association is emphasised, which has made the practice of acupuncture without a qualification an abusive exercise of the medical profession. With sentence no. 2258 of 27 March 2003, the sixth section of the Criminal Court of Cassation specified that

Acupuncture, like other therapies such as homeopathy, homotoxicology, phytotherapy and other homologous therapies, is counted among the 'unconventional' therapeutic practices which require specific knowledge of medical science and which carry out a health activity consisting in a diagnosis of an organic alteration or functional disorder of the body or mind and in the identification of remedies and their administration by the doctor himself or by paramedical staff under the doctor's supervision. A medical degree is required to practise acupuncture: anyone practising acupuncture without such a qualification commits the offence referred to in Article 348 of the Criminal Code aimed at protecting public health. In fact, although acupuncture is not a subject taught in Italian universities, it can only be practised by doctors or surgeons, knowledge of medicine or surgery being necessary to make an exact diagnosis and to avoid harmful consequences for the patient.²⁵

It is also pointed out that acupuncture is an invasive practice, which, in addition to the typical hypnotic and anaesthetic effect that it causes on the patient, is exposed to all the risks connected with an intervention of this nature, such as that of serious injuries caused by invasion of inappropriate parts of the human body, not to mention the risk of infections due to the use of tools that have not been sterilised in compliance with the standards currently provided for and periodically checked by the health services.²⁶

As far as the official indications of the FNOMCeO are concerned, the first references to unconventional medicine are to be found in the 1998 Code of Medical Deontology, under Title II – General Duties of the Physician, Chapter IV – Diagnostic Findings and Therapeutic Treatments – Article 13 Unconventional Practices – Reporting of Abuse. The article states that:

The power to choose non-conventional practices in respect of the decorum and dignity of the profession is expressed in the exclusive sphere of direct and non-delegable professional responsibility, it being understood, however, that any non-conventional therapy must not exempt the citizen from specific treatments of proven efficacy and requires the acquisition of consent. It is forbidden for the doctor to collaborate in any way or to favour those who abuse the profession even in the area of so-called 'unconventional practices'.

²⁴ https://apps.who.int/gb/ebwha/pdf_files/WHA56/ea56r31.pdf.

²⁵ ITALIAN COURT OF CASSATION, criminal 22528/03, in *Riv It Med Leg and Dir San*, 2003, 427.

²⁶ See ID, 6th criminal section, maximum sentence no. 482/2003.

Similar considerations are given by the 2006 Code of Medical Ethics, under Title II: General Duties of the Physician, Chapter IV – Article 15 Unconventional Practices.

On 12 December 2009²⁷ the National Council of the FNOMCeO revises the “Guidelines for Training in Non-Conventional Medicines and Practices reserved for Doctors–Surgeons and Dentists of the Health Commission-Conference State-Regions”.

This document was sent on 14 January 2010 to the Presidents of the Provincial Orders. Since the list was drawn up in 2002, all activities except Osteopathy and Chiropractic, as health professions that are not the exclusive domain of medical practitioners, remain the exclusive domain of medical and dental practitioners.

The code of medical ethics, deliberated by the FNOMCeO on May 18, 2014,²⁸ deals with unconventional medicines within Article 15: “Unconventional Systems and Methods of Prevention, Diagnosis and Treatment”, which states:

The physician may prescribe and adopt, under his direct responsibility, unconventional systems and methods of prevention, diagnosis and treatment while respecting the decorum and dignity of the profession. The physician shall not withdraw the person being treated from scientifically based and proven treatments. The physician shall ensure both the quality of his or her specific training in the use of unconventional systems and methods and circumstantial information for the acquisition of consent. The physician shall not cooperate with or encourage the practice of non-medical third parties in non-conventional disciplines recognized as exclusive and reserved activities of the medical profession.

In Italy, an important milestone in the regulation of the practice of acupuncture is represented by the Agreement between the Government, the Regions and the Autonomous Provinces of Trento and Bolzano concerning the criteria and modalities for the training and related practice of acupuncture, phytotherapy and homeopathy by surgeons and dentists.

With the State–Regions Agreement of February 7, 2013, indications are determined regarding the:

- Need to proceed with the quality certification of training in acupuncture, phytotherapy and homeopathy, identifying the minimum and uniform criteria and requirements throughout the country for suitable training paths.
- Identification of professionals practicing these activities, which, however, remain reserved to the competencies identified by state law to surgeons and dentists, veterinarians and pharmacists.
- protection of the health of citizens for which lists of professionals practicing Acupuncture, Phytotherapy and Homeopathy are established at the provincial professional orders of surgeons and dentists.

It is also important to refer to Law no. 24 of March 08, 2017 (so-called Gelli-Bianco):²⁹ “Provisions on the safety of care and the person being cared for, as well as on the professional liability of health profession

²⁷ https://portale.fnomceo.it/wp-content/uploads/import/201801/67825_linee-guida-fnomceo-formazione-nelle-medicine-e-pratiche-non-convenzionali.pdf.

²⁸ <https://portale.fnomceo.it/wp-content/uploads/2018/03/CODICE-DEONTOLOGIA-MEDICA-2014.pdf>.

²⁹ ITALIAN PARLIAMENT, Law no. 24 of March 08, 2017, *Gelli–Bianco*, available at this link: <https://www.gazzettaufficiale.it/eli/id/2017/03/17/17G00041/sg>.



practitioners”, which reformed medical liability. In particular, art. 5 (Good clinical care practices and recommendations under guidelines) and art. 6 (Criminal liability of the health profession practitioner) form the cornerstone of the new legislation.

Article 5 stipulates the obligation on health profession practitioners to follow the recommendations set forth in the guidelines or, in the absence of guidelines, the obligation to follow good clinical care practices.

Article 6 introduces into the Criminal Code article 590 sexies, relating to the case of manslaughter and culpable personal injury committed in the medical field. The new norm provides for a hypothesis of non-punishability of the doctor in the presence of specific elements:

if the event has occurred due to inexperience, punishability is excluded when the recommendations provided by the guidelines as defined and published in accordance with the law or, in the absence of these, the good clinical-assistance practices are complied with, provided that the recommendations provided by the aforementioned guidelines are appropriate to the specifics of the concrete case.

With the decree published in the Official Gazette on June 23, 2023³⁰ the new LEAs, essential levels of care, are approved. The National Health Service is required to provide in public health facilities, allowing citizens to request treatments included in the list. Among the specialist services, we find acupuncture for analgesia and other forms of acupuncture in the catalogue.

For other indications, supported by scientific literature, services not included in the national LEA declaratory, some regions have planned to use their own resources to provide additional services. Examples are:

- The Region of Val D’Aosta that by Council Resolution no. 1241 of 09/13/2019,³¹ in Art. 15 Acupuncture services provides that:

The Azienda USL Valle d’Aosta is authorized to provide, upon prescription of the specialist physician, with charges borne by the SSR, outpatient acupuncture services, limited to those aimed at the treatment of: nausea and vomiting in pregnancy; side effects of therapy in the cancer patient; migraine headache and painful manifestations of the chronic musculoskeletal and osteoarticular system, on prescription of the specialist algologist, following failure or contraindication to common pain-relieving therapies

- The Emilia–Romagna Region by Council Resolution 714 of 26.05.2014³² Resolves that:

The services identified by OMNCER, referred to in M.D. July 22, 1996 and Oct. 18, 2012, cod 99.91 “acupuncture for anaesthesia” and cod 99.92 “other acupuncture,” are as follows: Acupuncture: Recurrent or chronic lumbar musculoskeletal pain, with or without sciatalgia; Acupuncture: Prophylaxis of musculoskeletal headache; Acupuncture: Prophylaxis of migraine headache.

- The Region of Tuscany by Resolution of the Regional Council no. 674 of 2014³³ amends the Regional Tariff Nomenclator of Outpatient Specialty Care Services, for the part relating to complementary medicine services, providing the following services:

³⁰ <https://www.gazzettaufficiale.it/eli/gu/2023/08/04/181/sg/pdf>.

³¹ <https://bit.ly/3Lsbw8e>.

³² <https://bit.ly/4jE2H7T>.

³³ https://www.amabonline.it/images/DOCUMENTI_LEGALI/39.delibera_674-2014-.pdf.

manual medicine manipulations;

- acupuncture combined with other techniques such as: moxibustion, plum blossom needle, electrostimulation, auriculotherapy, scalp acupuncture and cupping;
- acupuncture, moxibustion, plum blossom needle, auriculotherapy, scalp acupuncture and cupping;
- pediatric tuina.

5. Discussion

Acupuncture is considered for all intents and purposes to be a valid and safe therapeutic technique. Based on data in the literature, it has long been recommended and recognized for chronic³⁴ or painful conditions.³⁵ In addition to these therapeutic indications, there are many other conditions that can benefit from acupuncture, such as sleep disorders,³⁶ hot flashes³⁷ during menopause, and side effects of anticancer drugs or cancer symptoms.³⁸

Currently, benefit has also been recognized for the use of acupuncture in some complex pain syndromes such as fibromyalgia³⁹ or in the rehabilitation of post ischemic stroke patients.⁴⁰

Legal recognition of this discipline is of crucial importance to the acupuncture practitioner's practice and to the protection of the patient who benefits from the treatments. Certainly, the legal status of acupuncture must be evaluated according to the principle mentioned before, according to which an unconventional practice is considered a medical act in two eventualities: 1) when it is made the subject of university teaching, or 2) of jurisprudential decisions explicitly qualifying it as a medical act.

According to the aforementioned rulings of the Sixth Section of the Criminal Cassation, the most recent of which is no. 22528 of 2003, the practice of acupuncture received legitimacy from the second eventuality. However, a point of decisive interest is the reference to university educational regulations used as a guide to determine the scope of competence of a profession (given by the Criminal Cassation, 6th section, no. 482 of March 27, 2003). In the same, it is noted that the University of Rome "La Sapienza", since the beginning of this century, has activated a Level II Master's Degree in Acupuncture, whose qualification for admission is the master's degree in medicine–Surgery and Dentistry.

Thus, the legal status of this NCM appears to depend now on the first eventuality between the two hypotheses mentioned above: that is, acupuncture is a medical act insofar as it is contemplated by a uni-

³⁴ XXXIV AIAM NATIONAL CONGRESS OF ACUPUNCTURE, *Professional Responsibility in Acupuncture and Traditional Chinese Medicine and Proposed Guidelines for the Treatment of Osteoarticular Diseases*, April 2021, "Sapienza" University of Rome.

³⁵ M.S. WU, K.H. CHEN, I.F. CHEN, *et al.*, *op. cit.*

³⁶ S.A. KIM, S.H. LEE, J.H. KIM, *et al.*, *op. cit.*

³⁷ T. LI, Y. ZHANG, Q. CHENG, *et al.*, *op. cit.*

³⁸ M.A. FANGFANG, Z. HEWEI, L.I. BINGXUE, C. PEIYU, Y.U. MINGWEI, W. XIAOMIN, *Acupuncture and moxibustion for malignant tumor patients with psychological symptoms of insomnia, anxiety and depression: a systematic review and Meta-analysis*, in *J Tradit Chin Med*, 43, 3, 2023, 441–56.

³⁹ J.A. VALERA–CALERO, C. FERNÁNDEZ–DE–LAS–PEÑAS, M.J. NAVARRO–SANTANA, G. PLAZA–MANZANO, *Efficacy of Dry Needling and Acupuncture in Patients with Fibromyalgia: A Systematic Review and Meta-Analysis*, in *Int J Environ Res Public Health*, 19, 16, 2022, 9904.

⁴⁰ L.M. CHAVEZ, S.S. HUANG, I. MACDONALD, J.G. LIN, Y.C. LEE, Y.H. CHEN, *Mechanisms of Acupuncture Therapy in Ischemic Stroke Rehabilitation: A Literature Review of Basic Studies*, in *Int J Mol Sci*, 18, 11, 2017, 2270.



versity course of study. Which undoubtedly invests it with a greater dignity, as a therapeutic instrument hitherto ambiguously tolerated, but contemplated by the legal system in order to realize in the most complete manner the citizen's right to health, where it takes the form of freedom of choice of the treatment deemed most appropriate.

It is barely necessary to point out that the possible provision of non-conventional medicine within the framework of vocational education and training courses set up by the regions is not equivalent to deeming them medical activities tout court, given that, as we have seen, only those disciplines covered in university teaching are medical. According to Article 33, Paragraph 6, of the Constitution, "Institutions of high culture, universities and academies, have the right to give themselves autonomous orders within the limits established by the laws of the State". Therefore, all universities, whether public or private, operate within the framework of state regulations that allow for the recognition of academic degrees in the national territory and therefore, by virtue of EU regulations, also in the European sphere.


This notwithstanding, the Regions certainly identify, for the purpose of accreditation, the subjects (associations, scientific societies, public and private training institutions using qualified professionals with specific curricular skills) within the "criteria and modalities for quality certification of training of the practice of acupuncture, of phytotherapy and homeopathy by surgeons, dentists, veterinary surgeons and pharmacists" as training subjects for 'the implementation of the Training Pathway in Acupuncture addressed to Doctors and Dentists' in accordance with the State-Regions Agreement of February 07, 2013, as well as continuing education and refresher training (so-called CME – Continuing Medical Education).

6. Conclusions

Traditional Chinese Medicine (TCM) is a comprehensive and unique medicine that has proven its effectiveness in many fields of prevention and health protection. Collaboration and integration between TCM and Western medicine could lead to a more comprehensive approach in taking care of the person ⁴¹ As of today, the inclusion of Acupuncture in the LEAs represents an important step forward for TCM and to guarantee an additional service to the patient and legally recognized following the inclusion of the discipline in university educational offerings, as was the case following the establishment of the Level II Master's Degree in Acupuncture at the "Sapienza" University of Rome.

The elements in the state of the facts in evidence are thus:

⁴¹ K. CHAN, X. HU, V. RAZMOVSKI–NAUMOVSKI, N. ROBINSON, *op. cit.*; L. ZHAO, K. CHAN, *Building a bridge for integrating Chinese medicine into conventional healthcare: Observations drawn from the development of the Chinese quality of life instrument*, in *American Journal of Chinese Medicine*, 33, 6, 2005, 897–902; N. ROBINSON, *The Importance of Evidence for the Integration of Traditional and Complementary Medicine into Western Healthcare?*, in *World Journal of Traditional Chinese Medicine*, 2, 1, 2016, 74–79; D.A. GUO, J.Y. HAN, *Integration of Traditional Chinese medicine and modern science is the way forward*, in *World Journal of traditional Chinese medicine*, 1, 2, 2016, 1; J. REN, X. LI, J. SUN, M. HAN, G.Y. YANG, W.Y. LI, N. ROBINSON, G. LEWITH, J.P. LIU, *Is Traditional Chinese Medicine Recommended in Western Medicine Clinical Practice Guidelines in China? A systematic analysis*, in *BMJ Open*, 5, 6, 2015; W. HUANG, D. PACH, V. NAPADOW, K. PARK, X. LONG, J. NEUMANN, *et al.*, *Characterizing Acupuncture Stimuli Using Brain Imaging with fMRI – A Systematic Review and Meta-Analysis of the Literature*, in *PLoS ONE*, 7, 4, 2012, e32960; J.S. HAN, Y.S. HO, *Global trends and performances of acupuncture research*, in *Neuroscience and Biobehavioral Reviews*, 35, 3, 2011, 680–87.

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- (a) unconventional medicines (Acupuncture, Homeopathy, Phytotherapy), in their application, insofar as they presuppose a diagnosis of an organic alteration or functional disturbance of the body or mind, fall within the scope of the medical act and therefore within the exclusive competence and jurisdiction of a physician;⁴²
 - (b) since acupuncture is recognized as an invasive practice, in compliance with the standards provided for and periodically verified by the health services, it cannot but fall exclusively within the scope of the medical act;⁴³
 - (c) is legally recognized following the inclusion of the discipline in university educational offerings;
 - (d) requires a quality certification of training identified through the minimum and uniform criteria and requirements on the national territory of suitable training paths.⁴⁴ This is especially in the identification of public and private training subjects participating in it;
 - (e) protection of the health of citizens for which lists of professionals practicing Acupuncture, Phytotherapy and Homeopathy are established at the provincial professional orders of surgeons and dentists.

⁴² See Presidential Decree no. 221 of April 5, 1950.

⁴³ Cf. maximum sentence no. 482/2003 Italian Court Cass., 6th criminal section.

⁴⁴ Cf. State–Regions Agreement of 07.02.2013.