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FORENSIC ASPECTS OF COMPLEMENTARY AND ALTERNATIVE MEDICINE (CAM)

ASPETTI MEDICO-LEGALI DELLA MEDICINA ALTERNATIVA E COMPLEMENTARE (CAM)

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Abstract

Background: In today's Italian scenario, the liberal professions – a term embracing both regulated (protected or recognized) and unregulated occupations – can represent an alternative to traditional employment, or be complementary to it.

In recent years, unincorporated professional associations have become a widespread phenomenon to the point that the NCEL (National Council for Economy and Labour) has worked out a list called «*Database of professional associations*» made up of approximately 200 associations, 42 of which included in the "Unconventional Medicine" category. However, since the jobs not falling within the professional associations category are failing to be given due consideration, proper dignity should also be recognized to the activities not regulated by professional registers.

Objectives: The authors of this study have examined the current Italian legislation associated with the use of alternative medicine practices in order to illustrate the need for a definitive legal framework of the subject setting clear rules for the use of unconventional treatments.
The acronym CAM (Complementary and Alternative Medicine) has recently come into force in the Anglo-Saxon world to describe a group of different medical and therapeutic practices which, while not considered as part of conventional medicine, are nonetheless not in contrast to it.
In the wake of this new acronym, even in Italy these medical practices, which go under the name of "Integrated Medicine", are gaining growing popularity.

Methods: The authors have analyzed the possibility to integrate the practices of conventional medicine with traditional medicine in public clinics and have to that end mentioned the experimental model of some regions, such as Emilia Romagna and Tuscany, as an example. Furthermore, based on the final judgment rendered in the "Di Bella" case, the authors emphasize that, despite the widespread national practices of alternative medicine, the latter must be supported by evidence of how effective these can be in order to be provided by public clinics and therefore be borne by the NHS.

Results and Conclusions: Whereas the unconventional practices are areas fully and legitimately part of the professional health, it is desirable to come to a permanent legal framework in this area, setting clear rules for unconventional treatments, in order to guarantee to citizens who choose such treatments the competence of those who practise them as well as ensuring to the professionals working in this field the opportunity to stand out from figures without adequate experience.

Abstract

Introduzione: Attualmente, nello scenario italiano le libere professioni - che si dividono in regolamentate (protette o riconosciute) e non regolamentate - possono essere alternative al tradizionale lavoro dipendente, oppure complementari ad esso.
Negli ultimi anni è emerso il fenomeno delle associazioni professionali non riconosciute, tanto che il CNEL ha stilato una lista di “Banca dati sulle associazioni professionali”composta da quasi 200 associazioni, tra cui 42 comprese nella categoria “Medicine non Professionali”. Tuttavia, dato che il lavoro svolto al di fuori degli ordini professionali vive una situazione di scarsa considerazione, sarebbe necessario riconoscere un’adeguata dignità anche all’attività professionale svolta al di fuori degli Albi professionali.

Obiettivi: In questo studio gli Autori esaminano l’attuale normativa italiana relativa all’utilizzo delle pratiche di medicina alternativa allo scopo di illustrare la necessità di un definitivo inquadramento normativo della materia che stabilisca regole certe per l’utilizzo dei trattamenti non convenzionali.
Recentemente, nel mondo anglosassone è entrato in vigore l’acronimo CAM (“Complementary and Alternative Medicine”), ovvero un gruppo variegato di pratiche mediche e terapeutiche che non rientrano nell'alveo della medicina convenzionale, ma che non si pongono nemmeno in contrapposizione con la “Medicina Convenzionale”, intesa come medicina accademica. Sulla scia di questo nuovo acronimo, anche in Italia sta diventando sempre più comune definire tali pratiche con l’espressione di “Medicina Integrata”.

Metodi: Gli Autori analizzano la possibilità di integrare le pratiche di medicina non convenzionale con la medicina tradizionale all’interno degli ambulatori pubblici, portando ad esempio il modello sperimentale di alcune Regioni, quali l’Emilia Romagna e la Toscana. Inoltre, esaminando l’ultima Sentenza sul caso “Di Bella”, sottolineano come, nonostante la larga diffusione a livello nazionale delle pratiche di medicina alternativa, queste ultime devono essere

supportate da prove di effettiva efficacia affinché possano essere erogate da ambulatori pubblici e, di conseguenza, essere a carico del Servizio Sanitario Nazionale.

Risultati e Conclusioni: È auspicabile che si approdi ad un definitivo inquadramento normativo della materia che stabilisca regole certe per i trattamenti non convenzionali, in modo da garantire ai cittadini che optano per tali trattamenti la professionalità di chi li pratica e agli stessi professionisti la possibilità di distinguersi da figure prive di adeguata professionalità.

In conclusione, considerando che le pratiche non convenzionali costituiscono un settore che legittimamente e a pieno titolo rientra nell'ambito dell'attività professionale sanitaria, l'integrazione delle pratiche non convenzionali all'interno del sistema convenzionale della medicina garantirebbe ai cittadini la più alta libertà di scelta terapeutica, assicurando loro il più elevato livelli di sicurezza e di correttezza di informazione.

Background

Currently, the liberal professions represent a complex reality in Italy: as a matter of fact, even if they merge into the self-employed category, they can be also an alternative to traditional employment or complement it.

Moreover, pursuant to current legislation, they can be divided into *regulated and unregulated* professions. The former ones include the so-called *protected* professions, which require the professional to be member of a register as well as the establishment of a professional association, entrusted with the control of the activity; and the *recognized* professions, governed by law and which require the professional to be member of registers or lists but do not contemplate a professional body.

Unregulated professions, on the other hand, while accounting for an important social and economic reality, are not subject to public regulations, even if they are present on the job market and are represented only by the relevant associations (1).

Table 1

Professions	**Associations**
Arts, technical sciences	25
Business communications	18
Business services	52
Unconventional medicine	42
Sanitary	19
Psychological care	16
Other	24
Total	**196**

For the last ten years the NCEL (National Council for Economy and Labour) has been paying special attention to emerging professions and has consequently drawn up a list called «*Database of professional associations*», formed by 196 associations, categorized as described above (Table 1).

In particular, the «*unconventional medicine*» category includes a total of about 100,000 members: music therapists, *feldenkrais* method teachers, natural hygienists iridologists *heilpraktiker*, naturopaths, holistic energy experts, shiatsu operators, body energy techniques, yoga experts, pranotherapists, flower therapists, herbalists, mind- body connection analysts, kinesiologists, foot reflexology experts, biotherapists, integrated medicine experts.

Therefore, also thanks to the NCEL , unincorporated professional associations have recently become a widespread phenomenon, remarkable both for their numbers and in quality, as well as for their social relevance.

Furthermore, since the jobs not falling within the professional associations category are failing to be given due consideration in our country, thus exposing the State to the risk of infringement proceedings by the European Union, proper dignity should be also recognized to the activities not regulated by professional registers (2).

Non Conventional Medicine (NCM) versus Complementary and Alternative Medicine (CAM)

In 1995 the Italian National Federation of Councils of MDs and Dentists (FNOMCeO) used the term "alternative medicine or practice" to refer to «*...all those practices that claim to cure with methods other than those based on evidence gathered using the scientific method...*» (3).

The expression "Non Conventional Medicine" (MNC) is instead used to embrace a whole set of therapeutic methodologies ranging from acupuncture / traditional Chinese medicine to homeopathy, from homotoxicology to ayurvetic medicine, from chiropractic to osteopathy, from herbal medicine to anthroposophic medicine, from naturopathy to reflexology, from aromatherapy to chromotherapy, from Shiatsu to pranotherapy, from macrobiotics to yoga, from emotherapy to music therapy, ending with gemmotherapy: this is a very heterogeneous group of healing practices - some of which boasting a centuries-old tradition, while others more recently introduced - which fall outside the standard medicine practices and which have recently witnessed a growing interest in the Western world (4).

The first nine practices were picked out by the WHOa and by the European Parliament and were recognized by the above-mentioned FNOMCeO in the National Council of May 18, 2002 - as "relevant" on the Italian territory, since they turned out as being the most appreciated and demanded by the population as well as for their well-established tradition, although purely empirical in most cases (5, 6).

The Professional Ethical Code of the Italian MDs and Dentists in force since 2006 sets clear limits and roles for the use of Non-Conventional Practices - particularly in Chapter IV which illustrates diagnostic tests and treatments –: «*... the recourse to non conventional practices forms an inseparable part of the profession's decorum and dignity and belongs exclusively to the direct non-delegable professional responsibility of the doctor. The recourse to non conventional practices must not divert the citizen from specific, scientifically consolidated therapies and always calls for properly informed consent. Doctors are forbidden to collaborate in any way with, or promote the practice of, third parties not of doctor status in the sector of so-called non conventional practices.....''* (7).

The growing interest in NCM revolves around its basic requirements: the centrality, complexity and wholeness of the person according to a "holistic" approach, which focuses on the interaction between body and mind, the personalized and individualized therapy; the vision of the disease as the result of an imbalance inside the body, purporting to restore the person to harmony ; finally, the belief that the recourse to these medicines might minimize the risk of toxicity compared to the classical pharmacological industrial remedies (8).

In conclusion, the term "non conventional" turns out to be the most commonly used in Italy , which, however, risks to create a conflict between these treatment methods and the so-called "Conventional Medicine", used to refer to academic medicine.

In order to overcome this problem, the Anglo-Saxon world has recently unveiled the name CAM which is actually an acronym for "Complementary and Alternative Medicine" to include medical products and practices that are not part of standard care (9, 10).

In the wake of this new acronym, far more representative and appropriate than the previous ones, the above-mentioned medical practices have come to be known even in Italy with the name of "Integrated Medicine".

Indeed, this Medicine combines the values expressed by citizens with the doctor's values as well as with those of any other health care professional, thus meeting the requirements of social justice and maximum sustainability. Integrated Medicine incorporates several relevant aspects: a reasonable use of scientific knowledge, understanding of the situations and problems of the individual, relational sensitivity in view of encouraging mutual understanding, the ability to listen to and value the opinion of the patient (11).

Difference between the International Standards and the Italian Standards: from a "tolerant" system to an "exclusive" system

While most of the EU countries have joined a "tolerant" system, basically opting for scientific medicine but nonetheless accepting, to some extent, NCM practices, Italy still belongs to an "exclusive" system.

Indeed , while in a “tolerant” system various legal guidelines have been laid down to govern NCM practices, which have long been co-existing with standard care, in an “exclusive” system like the Italian, only medicine, surgery and dental

graduates and health professional degrees are recognized and none of these training programs contemplates NCM teaching (12).

In 1992, as a result of the legislative heterogeneity of non-conventional treatments in the Western world, combined with the growing recourse to NCM practices, the European Parliament adopted a "Motion for a resolution" (13) urging for the precise identification and classification of " non-conventional medicines and therapies. "

Furthermore, on May 29th 1997, the European Parliament issued the "Resolution on the status of non-conventional medicine" (14) which, in the light of and in accordance with the previous proposal, promoted a health policy substantially open to unconventional practices, calling on member states to fulfill their commitments towards the recognition of these methodologies (15) and focusing on the importance of ensuring to patients a wide range of treatments, an adequate level of safety and thorough information on the quality, effectiveness and risks associated with these procedures.

Moreover, the European Parliament has ensured funds allocations for the prosecution of scientific studies on non-conventional therapies, thus urging a concrete commitment from every member state in favour of the integration of CAM in official medical care.

In spite of the large number of bills proposed in the recent decades, Italy is currently still lacking a specific legislation governing Non-Conventional Medicine. Indeed, several legislative proposals were discussed during the recent legislatures but none of them has been fully developed yet.

For example, in 1997 as a result of the bill entitled "*Discipline of unconventional therapies and setting up of unconventional practitioners registers*», the diagnostic and therapeutic value of nine NCM was acknowledged as well as the development of specific courses within the Medicine and Surgery degree program , post-graduate courses of specialization and registers of professionals.

Unfortunately, despite the numerous attempts, this bill failed to be passed.

The result is a paradox, since NCM practices are currently carried out in a mostly privatized regime, mainly by professionals, doctors or otherwise, without an officially recognized training. These professionals cannot use the title "specialist" and they sometimes prescribe drugs which lack an adequate regulatory iter for market approval.

Furthermore in Italy, with regard to the training of these practitioners, the study programme at the Faculty of Medicine and at Post-Graduate Schools does not contemplate any education course , hence the required training is assigned to private bodies that organize postgraduate masters and short courses (8).

A possible step forward: bills discussed in 2011 on homeopathy, traditional Chinese medicine and acupuncture

Since the National Health System wished to take also into consideration NCM , Article 9 of Legislative Decree 229/1999 – on NHS supplementary funds – mentioned them as possible additional services, while failing to include them among the minimum healthcare provisions.

The following step was during the National Council of FNOMCeO of 18th May 2002, when it was stated that «*...the exercise of these medicines and unconventional practices represents to all effects and purposes a medical act...*» and that «*... the doctor and the dentists are the only health care providers entitled to identify patients likely to get benefits whatsoever ... the only people entitled to make diagnosis, to draw up the appropriate treatment plan and monitor its implementation on the patient...*».

In 2006 the EU, which had long been committed to ensuring an adequate level of protection, competitiveness and innovation in health matters, enacted the "Directive on drugs and medicines" aimed at ensuring the compliance, within the framework of all member states, with the regulatory and marketing procedures of new classes of drugs.

In Italy, however, despite the EU Directives, the administrative act containing the authorization to register a new homeopathic drug has not been formalized yet (16).

Consequently, in order to overcome this limitation, a large number of bills were deposited in Parliament with the intent of obtaining a legal recognition of CAM, which result could not be achieved also due to the continuous interventions of the National Bioethics Committee (17) that, at a meeting on 18 March 2005 ruled against Alternative and Complementary Medicine - and of the Italian Episcopal Committee (IEC), that had spoken out against Oriental Disciplines for religious-theological considerations.

The above-mentioned «*Resolution and Guidelines on Medical and Non-Conventional practices*» as integrated by the «*Training guidelines on non conventional medicine and practices ....*» - approved by FNOMCeO National Council of December 12, 2009 - highlights that only the medical doctor and dentist are qualified to exercise non-conventional medicines and practices, proposed to adequately informed patients, who may actually get benefits from them; it is also recommended to develop educational initiatives to be included in Continuing Medical Education programs (18).

On 6 April 2011, two bills were presented to the Senate concerning traditional Chinese medicine and acupuncture and homeopathy in order to regulate the exercise of these CAM (19).

Proposal for integration with traditional medicine in public clinics: Experimental Model in Tuscany and Emilia Romagna.

In Italy the so-called "alternative medicine" (NCM) which, for a number of reasons, is continuing to generate great interest among citizens and health care providers , is still lacking an adequate legislative framework clearly identifying NCM practices and fixing the boundaries of their use; similarly, criteria for qualifying persons authorized to practise them are still missing nor are they included in NHS services.

Indeed, the national context is characterized by a substantial regulatory gap and by the failure to set a framework law in past legislatures. The NCMs are not included in the National Health Service (20) nor are they mentioned in the list of integrative activities that may be provided with fee by the local health unit as out-patient services.

An integrated version of these projects is currently being developed but even if a national law is still missing, regions are gaining growing independence. As a matter of fact, in the light of NCM increasing popularity, the Regions have adopted several initiatives in an attempt to regulate a much varied sector, especially within the Health Service. In fact, even in accordance with the revisions to Title V of the Constitution (21), some Regions have taken specific NCM-associated initiatives , with very different approaches. In some cases, NCM practices were mentioned in the Regional Health Plans, in other cases regional facilities were made available as a reference (committees, observatories, technical and scientific committees, etc..); or else, research programs were funded or promoted and information campaigns and training for doctors and other health care providers were carried out.

In many areas, like Lombardia , Emilia Romagna, Toscana, Piemonte and Lazio, NMC treatments are provided at public clinics, particularly acupuncture and homeopathy.

Toscana is at the forefront of NMC promotion, since it approved a resolution on Acupuncture, Homeopathy-Homotoxicology, Herbal Medicine and Manual Medicine thereby including them among minimum healthcare provision services: in practice they would be delivered, based on a specific tariff plan, by the NHS upon request of the GP hence making it possible for citizens to access these therapies as well as developing research.

Furthermore, the “Regione Toscana” has decided to implement other measures such as: regulating the training of non conventional medical practitioners , ensuring good quality standards; including NCM representatives within the Regional Health Council and the Health Councils of hospitals and universities and approving a supplementary agreement so as to regulate the activities of specialist outpatient services, thereby ensuring qualified professionals to the local health units.

Moreover, the “Regione Toscana”, has set up a continuous monitoring activity of NCM practices in view of assessing their effectiveness and in such a way as to complement the techniques likely to improve the health of citizens while at the same time allowing the proper allocation of available resources (22).

Emilia-Romagna is another much involved region in this field; indeed, it has enacted a specific legislation, has set up an observatory for non-conventional medicine (OMNCER) with qualified experts and, most of all, it has promoted a research program for the integration of NCM in the Regional Health Service (23).

A recent Judgment on the “Di Bella” method.

Among the various forms of alternative medicine, the "MDB" (or "*multi-therapy Di Bella*", abbreviated MDB) sparked the Italian media’s interest between 1997 and 1998. The MDB is an alternative therapy for the treatment of cancer, whose effectiveness is not supported by any scientific evidence (24).

The reasons behind such a large media coverage are to be found in the attraction for any treatment option allegedly providing a solution to a widespread (with more than 250,000 cancer diagnosis cases reported in Italy every year) and severe (accounting for 30% of the causes of death and with a 5-year survival rate estimated at about 40%) problem with far-reaching physical and emotional implications . On the other hand, the interest aroused by the so-called non-

conventional therapies appears to involve a growing number of people, considering that, as witnessed by recent investigations (25), more than 30% of patients opt for this type of treatment.

The founder of this method started his research on cancer in 1963 and four years later he began experimenting on some patients. In 1977 he introduced Somatostatin in his multitherapy as an alternative treatment of tumor masses and for the prevention of metastases.

Although in 1996 the National Cancer Commission had declared this therapy as devoid of proven scientific evidence and in 1998 the Constitutional Court had ruled against it , under the weight of the media coverage (26) and of the social alert aroused by the case, the Italian Government authorized the implementation of trials on January 10th, 1998. In this respect, it is worth quoting from the judgment rendered by the Constitutional Court on MDB «...Whenever ... there is the possibility of a treatment already tested and valid, it would not be reasonable to claim that the State should be required to provide for free other medical services, even only purportedly effective. As a matter of fact, the National Health Service cannot be expected to shoulder the burden of the consequences arising from free individual choices about the preferred therapy; anything else would represent a disclaimer of the role and responsibilities pertaining to the State through its scientific-technical health bodies responsible for testing and certifying the effectiveness, and non harmfulness, of pharmaceutical substances and their therapeutic use for public health protection ...» (27).

Shortly after, 11 phase-II multicenter studies were set up (aimed at assessing whether a specific treatment was capable of reducing the size of tumor masses in a significant number of patients) on eight types of neoplasms. The final assessment was entrusted with the "Italian Study Group for the Di Bella Multitherapy trial" which came to the conclusion that the experiments had not produced any supporting evidence in favour of further clinical trials. In conclusion, phase-II study showed that MDB did not have sufficient clinical activity to warrant further investigation, ie phase III.

The choice of a phase-II trial was actually dictated by relevant ethical and practical reasons. A Phase-III trial would, in fact, have involved a large number of patients : submitting, for a presumably long period of time, thousands of patients to a treatment with an *a priori* unknown effectiveness would have represented a breach of fundamental ethical constraints. Moreover, the journal *Cancer* reported an average life expectancy of patients treated with the Di Bella therapy shorter than those treated with traditional therapies of proven effectiveness (28) and also pointed out that such a treatment was not devoid of side effects (29).

Despite the failure of the trial, the public opinion continued to get closer to this alternative medicine (30) while at the same time all the media went on putting great emphasis on Dr. Di Bella, to the point that on February 15th , 1998, 15,000 Di Bella supporters rallied in his favour to get a free of charge therapy .

In the following years, the experimentation suffered a new setback: indeed, in 2003, the Chamber of Deputies approved a measure in favour of a new experimentation of the method (31) but in 2005 the National Institute of Health rejected this proposal thus blocking the trials again. To date, the method is publicized through various websites by Di Bella's children who have also set up a foundation (32).

Recently, on 26th February 2012, the method Di Bella was once more in the spotlight following the decision of a Judge of the Labour Court of Bari, Maria Procoli, who upheld the appeal lodged by a cancer patient who asked to be treated with the Di Bella method.

With this ruling, the judge reiterated the right of the patient to use the somatostatin-based cocktail of drugs developed by Dr Di Bella against the tumor. The Court of Bari has in fact upheld the request of a patient thus obliging the «*Local Health Unit to grant immediate disbursement and free drug treatment*».

However, the judgment in favour of the Di Bella method was short-lived, since the General Manager of the Local Health Unit, M. Domenico Colasanto, signed a resolution to proceed with an appeal and contest the judge's decision.

As a matter of fact, a recent Judgment of the Labour Appeal Court of Bari admitted the claim presented by ASL thereby reversing the judgment of first instance issued in February, stating that: «*...The effectiveness of the Di Bella therapy is not supported by scientific evidence and therefore you can not force the NHS to supply it free of charge to anyone asking for...*».

Accordingly, the judgment confirms that, despite the broad national popularity of NCM practices, they must be supported by substantial evidence demonstrating their effectiveness so that they can be provided by public clinics and, consequently, be borne by the National Health Service. If it is true that you can not prevent a patient from choosing the type of therapy to follow - the right to health is a primary and fundamental right of the individual – it is likewise

undeniable the groundlessness of a subjective right to ensure that public health care structures take an active part in the provision of therapies whose effect is not scientifically recognized (33).

As concerns the limited resources and minimum healthcare standards provided, in 1995 the Constitutional Court had already stated quite categorically: «*...In the presence of limited resources and reduced availability of funds associated with the need for fiscal consolidation, unlimited expenditure - only determined on the basis of the needs - is out of question, however severe and urgent they may be; on the contrary, it is expenditure that has to be proportionate to the existing economic resources, which affect the quality and the quantity of health care services and to be determined in the light of the priorities set and taking into account the fundamental need to protect the right to health, which cannot be undermined in any way by the measures currently under exam...*» (34). Therefore, the ordinances authorizing the provision of the Di Bella therapy drugs had totally disregarded obvious principles in the medical and legal areas.

In conclusion, the Di Bella case clearly witnesses the profound sense of distress investing the doctor-patient relationship which indeed suffers from a general lack of confidence in the medical profession generated, on the one hand, by the progressive loss of a direct dialogue with the patient and, on the other, by the firm belief in the infallibility of human progress. Any medical failure is now interpreted as a serious fault of healthcare . Such a distrust is the scenario underlying the Court decisions orientation, where a proven but, unfortunately, sometimes fallible medical treatment, is offset by practices whose therapeutic efficacy is uncertain , whose greatest merit is the alleged but never proven improvement in the quality of life, perhaps due to the interruption of the administration of a multidrug at high doses, rather than to the effectiveness of the Di Bella treatment (33).

Considerations and Conclusions

Given the growing recourse to alternative medicine practices, doctors ought to be culturally prepared to steer between conventional and non-conventional therapies, at least in the cases where the efficacy or better tolerability of the latter is demonstrated, even in the light of the recent case law orientation, on the issue of medical responsibility, which appears to focus also on the health risk increase associated with the type of treatment of choice. In fact, we cannot fail to consider the possibility of a request for compensation should a iatrogenic damage occur following a conventional treatment (as it could be the case after a prolonged use of corticosteroids, NSAIDs, antibiotics) that could have been avoided by having recourse - with the same effect – to an unconventional treatment (12).

It is therefore urgent that the Italian University, which is institutionally entrusted with the training of health workers, includes in the programs of the Medicine and Surgery degree courses, the base conceptual premises and technical aspects associated with the implementation of unconventional treatments, which are still lacking a scientific validation (35) and, most of all, the setting up of specific provincial registers reserved to unconventional medicine practitioners.

Recently, in the wake of the increasing popularity of "Complementary and Alternative Medicine", some Italian universities have set up a master level degree about the CAM receiving greater recognition from the scientific world. In particular, the Department of Social Medicine, Faculty of Medicine, University "Sapienza" of Rome has established a Master's Degree entitled "Acupuncture and Herbal Medicine integration of Traditional Chinese Medicine and Western Medicine" (36, 37). Moreover, like "Sapienza" also other Italian universities - in particular Bologna, Trieste, Cagliari (38) and Siena (39) have organized II level master degrees primarily on acupuncture, herbal medicine and homeopathy.

The University of Bologna has recently launched, thanks to the funds provided by the Regional Programme on NCD, two higher education courses which were also attended by health professionals of the Regional Health Service. One of the two advanced courses about NCM promoted by the University of Bologna, entitled "Integration of knowledge in conventional and unconventional medicine", was organized by the Faculty of Medicine in the academic year 2006-2007. It is aimed at health professionals or other, and aims to develop the skills necessary to guide the choices of health care organizations in NCMs. The other course "Sociology of Health and non-conventional medicine" (40, 41) is proposed by the University of Bologna, Department of Sociology .

Therefore, it is desirable to come to a permanent legal framework in this area, setting clear rules for unconventional treatments, in order to guarantee to citizens opting for such treatments the competence of those who practise them as well as ensuring to the professionals working in this field the opportunity to stand out from figures without adequate experience.

In conclusion, whereas unconventional practices are areas legitimately and fully falling under healthcare professional activity, the integration of unconventional practices within the conventional system of medicine would guarantee citizens the highest freedom of choice of treatment, giving them the highest levels of safety and correctness of information (42).

References

1. Art. 2222 c.c.: Contratto d'opera (Capo I: disposizioni generali; Capo II: delle professioni intellettuali risp.); artt. 2229 e seguenti c.c.: Professioni intellettuali.
2. Imola D. Professioni: un universo complesso. Nota del Dipartimento Politiche Economiche della CGIL, 1-13.
3. Art. 28 Commentario al Codice Deontologico, 1995.
4. Fineschi V, Frati P, Barni M. La lunga marcia della medicina alternativa verso le categorie della scienza e della responsabilità. Resp Civ Prev 1999; 1197-1222.
5. Introna F. Aspetti Medico-Legali della situazione italiana sulle Medicine Non Convenzionali per il 3° millennio. Riv It Med Leg 1999; 21: 109-146.
6. Introna F. Le Medicine Non Convenzionali (Delibera del Consiglio Nazionale della FNOMCeO, Terni, 18 maggio 2002). Riv It Med Leg 2002; 24: 1575-1589.
7. Art. 15 Commentario al Codice Deontologico, 2006.
8. Castiglioni C, Pellegrini M, Marchesi M, Morini O. Considerazioni medico-legali sulle medicine non convenzionali. Jura Medica 2007; 1: 7-27.
9. Angell M, Kassirer JP. Alternative Medicine – The Risks of Untested and Unregulated Remedies. NEJM 1998; 339: 839-841.
10. Complementary and Alternative Medicine in the United States. The National Academies Press, Washington D.C., 2005; 196-201.
11. Cavicchi I, Per una Medicina Integrata, Argomenti e Postulati, Manifesto per la Medicina Integrata. SIOMI 2011; 2 (2): 19-23.
12. Norelli GA, Bonelli A, Magliona B, et al. Aspetti medico-legali dei trattamenti non convenzionali. Riv It Med Leg 2002; 24 (2): 305-332.
13. Gazz. Uff. UE 13.10.1992, n. 297.
14. Gazz. Uff. UE 16.06.1997, n. 182.
15. Risoluzione del Parlamento europeo sullo Statuto delle Medicine non convenzionali. Riv It Med Leg 1998; 20: 113-117.
16. D.lgs 24 aprile 2006, n.219: Attuazione della direttiva 2001/83/CE (e successive direttive di modifica) relativa ad un codice comunitario concernente i medicinali per uso umano, nonché della direttiva 2003/94/CE.
17. Siamo ancora lontani dalla possibilità di una completa integrazione con le medicine convenzionale; infatti, il 23 aprile del 2004 il Comitato Nazionale di Bioetica ha bocciato il riconoscimento alle pratiche di medicina di medicina non convenzionale, perché prive di basi scientifiche. La decisione presa dal Comitato ha, innanzitutto, due effetti immediati: impedisce che le medicine alternative possano diventare materia d'insegnamento all'università o in corsi di formazione accademica e vieta la presenza di loro rappresentati vengano nominati nel Consiglio superiore di sanità, il massimo organo tecnico consultivo del ministero della Salute. E cade come un fulmine a ciel sereno sulla paventata possibilità di riconoscere una serie di discipline alternative, soprattutto per quello che riguarda il rimborso delle spese mediche da parte del Servizio Sanitario Nazionale.
18. Zuppiroli A, Etica delle cure integrate, Manifesto per la Medicina Integrata. SIOMI 2011; (2): 24-30.
19. Disegni di Legge 6 aprile 2011, n. 2672-2673:
    - Articolo 1: disciplina l'esercizio della CAM in questione nell'ottica del riconoscimento del pluralismo nella scienza e della ricerca scientifica;
    - Articolo 2: prevede l'istituzione, presso gli ordini provinciali dei medici, degli odontoiatri, dei farmacisti e dei veterinari, di appositi registri di esperti in tali discipline;
    - Articolo 3: istituisce, presso il Ministero della Salute, una Commissione permanente per la disciplina di tali CAM, con funzione consultiva presso il medesimo Ministero e con ilo compito principale di promuovere la corretta divulgazione delle tematiche sanitarie inerenti alle materie in questione e le attività di ricerca, anche al fine di riconoscere nuove discipline terapeutiche;

- Articolo 4: prevede la possibilità dell'accreditamento delle associazioni, società scientifiche ed enti privati di formazione ai fini della diffusione delle suddette Medicine Complementari;
- Articolo 5: stabilisce che il Ministero dell'Istruzione, dell'Università e della Ricerca istituisca corsi di formazione post-laurea al fine del rilascio della qualifica di esperti in omeopatia e medicina tradizionale cinese e agopuntura;
- Articolo 6: prevede la possibilità per lo Stato e le Regioni di procedere all'individuazione di nuove discipline complementari;
- Articolo 7: reca il principio del consenso informato, ovvero che il paziente che decide di sottoporsi a tali trattamenti, sia preventivamente informato dal medico circa diagnosi, prognosi, scopo e natura del trattamento sanitario proposto, comprensivo di benefici, rischi ed eventuali effetti collaterali ad esso legati.

20. Art. 9 D.lgs 19 giugno 1999, n. 229: Norme per la razionalizzazione del Servizio Sanitario Nazionale; all. 2 D.P.C.M. 29 novembre 2001: Definizione dei livelli essenziali di assistenza.
21. Art. 3 Legge Cost. 18 ottobre 2001, n. 3: "… Sono materie di legislazione concorrente quelle relative a: rapporti internazionali e con l'Unione europea delle Regioni; commercio con l'estero; tutela e sicurezza del lavoro; istruzione, salva l'autonomia delle istituzioni scolastiche e con esclusione della istruzione e della formazione professionale; professioni; ricerca scientifica e tecnologica e sostegno all'innovazione per i settori produttivi; tutela della salute; alimentazione; ordinamento sportivo; protezione civile; governo del territorio; porti e aeroporti civili; grandi reti di trasporto e di navigazione; ordinamento della comunicazione; produzione, trasporto e distribuzione nazionale dell'energia; previdenza complementare e integrativa; armonizzazione dei bilanci pubblici e coordinamento della finanza pubblica e del sistema tributario; valorizzazione dei beni culturali e ambientali e promozione e organizzazione di attività culturali; casse di risparmio, casse rurali, aziende di credito a carattere regionale; enti di credito fondiario e agrario a carattere regionale. Nelle materie di legislazione concorrente spetta alle Regioni la potestà legislativa, salvo che per la determinazione dei principi fondamentali, riservata alla legislazione dello Stato…".
22. Baccetti S, Rossi E, Firenzuoli F, Di Stefano M. Centro di Medicina Tradizionale Cinese Fior di Prugna. Notiziario Regionale delle Medicine Complementari, Centri regionali di riferimento. Rete Toscana Medicina Integrata 2011; 21 (8): 5-6.
23. Dossier 186-2009. Le Medicine non Convenzionali e il Sistema Sanitario dell'Emilia Romagna. Un approccio sperimentale. Servizio Sanitario Regionale Emilia-Romagna, 2009; 1-185.
24. Mori M. Epica e Medicina: il "caso Di Bella". L'informatore Bibliografico. Mulino Edizioni, Bologna, 1999; 330-340.
25. Bernardini S, "Integrativa", "Integrata" o Nuova Medicina?, Manifesto per la Medicina Integrata. SIOMI 2011; (2): 36-44.
26. Eco U. A passo di gambero: guerre calde e populismo mediatico, Bompiani, 2006.
27. Corte Cost. Sent. 20 maggio 1998 n. 185: Somatostatina gratuita ai malati indigenti fino al termine del ciclo di sperimentazione.
28. Traversa G. The unconventional Di Bella cancer treatment – A reflection on the Italian experience. Cancer 1999; 8(10): 1903-1911.
29. Pieroni BP. Sanità. Nuovo potere. Springer Verlag ed., 2004.
30. Un sondaggio dell'epoca sulla rivista Toscana Medica rilevava che l'85% degli italiani era favorevole alla cura Di Bella.
31. Seduta n. 314 del 27/5/2003.
32. Prof. Di Bella, criteriologia MDB, principi attivi, terapia, farmaci, monitoraggio, effetti collaterali, aspetti legali, diritti dei pazienti disponibili on line all'indirizzo: http://www.metododibella.org/it.
33. Frati P. Diritto alla salute, efficacia terapeutica e libertà di cura: a margine del caso Di Bella. Ragiusan, Rassegna Giuridica della Sanità 1998; 168 (11): 184-189.
34. Corte Cost. Sent. 28 luglio 1995 n. 416: Obbligo delle regioni di ripiano delle spese sanitarie.
35. ISTAT, Le terapie non convenzionali in Italia. Anno 2005, 2007, disponibile on line all'indirizzo: http://www.istat.it/salastampa/comunicati/non_calendario/20070821_00/testointegrale.pdf (22 apr. 2010).
36. Master di II livello istituiti dall'università "Sapienza" di Roma, disponibile on line all'indirizzo: http://www.emagister.it.

37. Second Level Master's degree of CAM to 3 addresses: "Traditional Chinese Medicine with Acupuncture, Homeopathy, Herbal Medicine". University of Rome and Bologna FIAMO (Italian Federation Associations and Homeopathic Doctors), disponibile on line agli indirizzi: http://www.uniroma1.it/didattica/master/agopuntura-fitoterapia-integrazione-tra-medicina-tradizionale-cinese-e-medicina e http://www.aosp.bo.it/content/attivit-integrata-di-agopuntura-e-medicine-non-convenzionali.
38. Second Level International Master's degree in Phytotherapy. University of Madrid, Trieste and Cagliari, disponibile on line all'indirizzo: http://www.masterfitoterapia.eu.
39. Second Level Master's Degree in Applied Phytotherapy. Italian Society of Phytotherapy, University of Siena, disponibile on line all'indirizzo: http://www.unisi.it/postlaurea/master.htm.
40. Integrazione fra saperi convenzionali e non convenzionali in medicina, disponibile on line all'indirizzo: www.unibo.it/Portale/Offerta+formativa/AltaFormazione/20072008/Integrazione fra saperi convenzionali e non convenzionali in medicina.
41. Sociologia della salute e Medicine Non Convenzionali, disponibile on line all'indirizzo: http://www.unibo.it/Portale/Offerta+formativa/AltaFormazione/2007-2008/Sociologia della salute.htm.
42. Gensini GF, Rossi E, Baccetti S, Willich S. Verso l'ideale terapeutico dell'umanizzazione della medicina. Notiziario Regionale delle Medicine Complementari, Centri Regionali di Riferimento, Rete Toscana Medicina Integrata, 2012; 24 (9): 2-6.

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