

## **Model Guidelines for the Practice of Complementary Therapies (CAM) by Medical Doctors in the European Union**

### **Introduction**

The practice of medicine in the modern era is beset with unprecedented challenges in virtually all cultures and societies. In Europe, one of the most important challenges is to take due account of the developed and creative pluralism of educational styles, nutritional methods, cultural and creative activities, scientific approaches and religious values. This pluralism, which embodies Europe's spiritual and cultural wealth, has increased still further through enlargement of the European Union to 27 member states. In medicine, the corresponding aspect of this is the wide variety of complementary medical approaches that exist alongside conventional medicine. The former pursue a holistic approach or intentionally integrate their complementary approach with conventional medicine. The complementary approach promotes, above all, the patients' own resources for restoring health. It is likely that this cultural and medical diversity can lead to the development of a rich potential for salutogenesis<sup>1</sup>, if the community of EU countries resolves to form its own autonomous health-promotion policy.

The following organisations represent 132 medical CAM associations across Europe:

- the European Committee for Homeopathy (ECH),
- the European Council of Doctors for Plurality in Medicine (ECPM),
- the International Council of Medical Acupuncture and Related Techniques (ICMART)
- the International Federation of Anthroposophic Medical Associations (IVAA).

They have a responsibility to ensure that their associated members utilize CAM in a manner consistent with safe and responsible medicine, in view of the increasing interest in and use of CAM therapies in medical practice.

The ECH, ECPM, ICMART and IVAA took the initiative, in January 2006, to develop model guidelines for the use of official medical licensing bodies (a) in educating physicians who use CAM in their practices, and/or those who co-manage patients with licensed or otherwise state-regulated CAM providers and (b) regulating their practice.

This initiative focuses on encouraging the medical community to adopt consistent standards, ensuring the public health and safety by facilitating the proper and effective use of both conventional and CAM treatments, while educating physicians on the adequate safeguards needed to ensure their services are provided within the bounds of acceptable professional practice. The ECH, ECPM, ICMART and IVAA believe that adoption of guidelines based on this model will protect legitimate medical use of CAM while avoiding unacceptable risk.

The intention of the Councils of ECH, ECPM, ICMART and IVAA is to provide guidelines that are clinically and ethically appropriate. These guidelines are designed

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<sup>1</sup> A concept that focuses on factors that support human health and well-being rather than on factors that cause disease; the term was coined by Antonovsky in 1979. See Lindström B et al (2005) Salutogenesis *Journal of Epidemiology and community Health*; 59;440-442

to be consistent with what official medical licensing bodies generally consider to be within the boundaries of professional practice and accepted standard of care.

In putting down these Guidelines the ECH, ECPM, ICMART and IVAA refer to similar Guidelines established in the United States of America in April 2002 (see references <sup>2</sup>).

## Section I. Preamble

The (*name of the licensing body*) recognizes that the practice of medicine consists of the ethical application of a body of knowledge, principles, methods and experience known as medical science and that these objective standards are the basis of medical approbation for European physicians. These standards allow a wide degree of latitude in physicians' exercise of their professional judgement and do not preclude the use of any reasonable therapeutic methods that are reasonably likely to benefit patients without undue risk. Furthermore, patients have a right to seek and obtain any kind of care they choose for their health problems. The licensing body also recognizes that a full and frank discussion of the risks and benefits of all medical practices is in the patient's best interest.

There are varying degrees of potential harm that can result from either conventional medical practices or CAM:

- Economic harm, which results in monetary loss but presents no health hazard;
- Indirect harm, which results in a delay of appropriate treatment, or in unreasonable expectations that discourage patients and their families from accepting and dealing with their medical conditions;
- Direct harm, which results in adverse patient outcome.

Regardless of whether physicians are using conventional treatments or CAM in their practices, they are responsible for practising good medicine by complying with professional standards and regulatory mandates. In consideration of the above potential harms, the (*name of the licensing body*) will evaluate whether or not a physician is practising appropriate medicine by considering the following practice criteria. Is the physician using a treatment that is:

- **effective and safe?** (having adequate scientific evidence of effectiveness and/or safety or greater safety than other established treatment models for the same condition)
- **effective, but with some real or potential danger?** (having evidence of effectiveness, but also of adverse side effects)
- **possibly effective, but safe?** (having insufficient evidence of clinical effectiveness, but reasonable evidence to suggest safety based on empirical data, traditional use, or bibliography)
- **ineffective and/or dangerous?** (proven to be ineffective or unsafe through controlled trials or documented evidence or as measured by a risk/benefit assessment)

Inasmuch as the (*name of the licensing body*) is obligated under European law to protect the public's health, safety and welfare and recognizes that the standards used in

evaluating health care practices should be consistent, whether such practices are regarded as conventional or CAM, the licensing body recognizes that a licensed physician shall not be prosecuted for practising medicine unprofessionally solely on the basis of utilizing CAM. Instead, the licensing body will use the following guidelines to determine whether or not a physician's conduct constitutes a violation of the European Medical Code of Conduct.

## **Section II. Definitions**

For the purposes of these guidelines, the following terms are defined as indicated:

### **Complementary and Alternative Therapies (CAM) in Medical Practices**

CAM is the worldwide used term for “A broad domain of healing resources that encompasses all health systems, modalities, and practices and their accompanying theories and beliefs, other than those intrinsic to the politically dominant health systems of a particular society or culture in a given historical period” (definition by the Cochrane Collaboration). People use CAM treatments and therapies in a variety of ways. Therapies may be used alone, as an alternative to conventional therapies, or in addition to conventional, mainstream therapies, in what is referred to as a complementary or integrative approach. Many CAM therapies are called holistic, which generally means they consider the whole person, including physical, mental, emotional and spiritual aspects. CAM therapies that are mostly practised by physicians can be found in annex 1.

### **Conventional Medical Practices**

Conventional medical practices refer to those medical interventions that are taught extensively at European universities, generally provided at European hospitals, or meet the requirements of the generally accepted standard of care in Europe.

## **Section III. Guidelines**

The (*name of the licensing body*) has adopted the following guidelines when evaluating the delivery or co-management of CAM:

### **1. Evaluation of the Patient**

Equivalent evaluation standards should be established for patients whether the physician is using conventional medical practices or CAM.

Prior to offering any recommendations for conventional and/or CAM treatments, the physician shall conduct an appropriate medical history and physical examination of the patient as well as an appropriate review of the patient's medical records. This evaluation shall include, but not be limited to, conventional methods of diagnosis and may include other methods of diagnosis as long as the methodology utilized for diag-

nosis is safe and reliable, and shall be documented in the patient's medical record. The medical record should also document:

- whether other, including conventional, medical options have been discussed, offered or tried, and if so, to what effect, or a statement as to whether or not certain options have been refused by the patient or guardian; that proper referral has been offered for appropriate treatment;
- that the risk and benefits of all therapeutic options to the extent known have been appropriately discussed with the patient or guardian;
- that the physician has determined the extent to which the treatment could interfere with any other recommended or ongoing treatment.

## **2. Treatment Plan**

The physician may offer the patient a conventional and/or CAM treatment pursuant to a treatment plan tailored to the individual needs of the patient by which treatment progress or success can be evaluated with stated objectives, such as pain relief and/or improved physical and/or psychosocial function. The treatment plan is documented and considers pertinent medical history, previous medical records and physical examination, as well as the need for further testing, consultations, referrals or the use of other treatment modalities.

The treatment offered should:

- have a favourable risk/benefit ratio compared to other treatments for the same condition;
- be based upon a reasonable expectation that it will result in a favourable patient outcome, including preventive practices;
- be based upon the expectation that a greater benefit will be achieved than that which can be expected with no treatment.

## **3. Consultation and/or Referral to Licensed or Otherwise State-Regulated Health Care Practitioners**

If necessary the physician may refer the patient for additional evaluation and treatment in order to achieve treatment objectives. This may include referral to a licensed or otherwise state-regulated health care practitioner with the requisite training and skills to utilize the CAM therapy being recommended. However, the physician should monitor the results and schedule periodic reviews to ensure progress is being achieved.

## **4. Documentation of Medical Records**

As expected of any physician using conventional medical practices or CAM therapies, he/she should keep accurate and complete records to include:

- the medical history and physical examination;
- diagnostic, therapeutic and laboratory results;
- results of evaluations, consultations and referrals;
- treatment objectives;
- discussion of risks and benefits;
- appropriate informed consent;

- treatments;
- medications (including date, type, dosage and quantity prescribed);
- instructions and agreements;
- periodic reviews;
- (if appropriate) patient's expectations about the therapy.

Records should remain current and be maintained in an accessible manner, and readily available for review stored at a safe place according to the standards for data and privacy protection.

## **5. Quality assurance**

Physicians providing CAM therapies should comply with the same quality standards as those physicians using conventional medical practices, both at the individual level and at the level of their professional group; these standards relate to education and training, registration, Continuing Professional Development, code of conduct and a complaints mechanism.

## **6. Clinical Research**

As expected of any physician using conventional medical practices or CAM therapies, he/she, while engaged in the clinical investigation of new drugs and procedures (medical research, research studies) is obligated to maintain their ethical and professional responsibilities.

Investigators shall be expected to abide by all common relevant guidelines including the Declaration of Helsinki, the WMA Medical Ethics Manual, Good Clinical Practice, and Good Epidemiological Practice.

Since CAM therapies typically treat an individual, not a disease, research should not be restricted to randomized trials of a specific CAM intervention or medical conditions that disregard the individuality of subjects. The full spectrum of clinical research methods (randomised, non-randomised, experimental and observational studies) is necessary to strengthen the quality and relevance of the evidence base in CAM.

## **In Conclusion**

The ECH, ECPM, ICMART and IVAA recognize that legitimate standards of medical practice are rooted in competent and reliable scientific evidence and experience. However, these standards are subject to continuous change and improvement as advances are made in scientific investigation and analysis. In addition, psychological, social, political and market forces influence standards of medical practice to some degree, and the provision of medical services in individual circumstances in particular. It is the responsibility of state medical licensing bodies to balance all of these considerations in fulfilling their obligation to protect the public through the regulation of the practice of medicine.

Public protection is carried out, in part, by ensuring physicians in all practices, whether conventional or CAM, comply with professional, ethical and practice stan-

dards and act as responsible agents for their patients. Accordingly, the ECH, ECPM, ICMART and IVAA encourage state medical licensing bodies to adopt these guidelines (a) to assist them in educating physicians who are (1) engaged in a practice environment offering conventional and/or CAM treatments; and/or (2) engaged in cooperative therapeutic relationships for their patients with a non-physician licensed or otherwise state-regulated health care practitioner offering CAM and (b) regulating their practice.

State medical licensing bodies should find a balance between the evidence-based principles of medical practice and the respect for the dignity of the patient and his freedom to choose autonomously. This balance should also ensure informed consent and minimize the potential of harm.

The ECH, ECPM, ICMART and IVAA reaffirm their commitment to cooperate with physicians and professionals, governmental and other organisations and agencies in supporting the further study of all promising health care practices.

## References

1. Model Guidelines for the Use of Complementary and Alternative Therapies in Medical Practice, approved by the House of Delegates of the Federation of State Medical Boards of the United States, Inc., as policy April 2002
2. Medical Professionalism in the New Millennium: A Physician Charter, published in *Annals of Internal Medicine*, vol. 136, n. 3, 5 February 2002
3. Consensus Conference “Non Conventional Medicine”, Consensus Document established during the 43<sup>rd</sup> National Congress of the Italian Psychiatric Association
4. Fähigkeitsprogramme der FMH (Swiss Medical Association) für: Akupunktur, Anthroposophische Medizin, Homöopathie, Neuraltherapie,
5. Spezialdiplome der Österreichischen Ärztekammer für: Akupunktur, Anthroposophische Medizin, Homöopathie und andere komplementärmedizinische Richtungen
6. Deliberazione della Federazione Nazionale degli Ordini dei Medici Chirurghi e degli Odontoiatri, Italia, 2002
7. Zusatzbezeichnungen Homöopathie, Naturheilverfahren, Manuelle Medizin, Chirotherapie, Physikalische Therapie, Balneotherapie ärztliche Weiterbildungsordnung Germany.
8. Zusatzbezeichnung Akupunktur, Novelle der ärztliche Weiterbildungsordnung, Deutschland, 2003.

## **ANNEX 1**

CAM therapies practised by physicians can be classified as follows, based on the classification by the National Centre for Complementary and Alternative Medicine in USA:

- **Alternative Medical Systems**

Alternative medical systems are built upon complete systems of theory and practice. Often, these systems have evolved apart from and earlier than the conventional medical approach used in the Western world. Examples of alternative medical systems that have developed in Western cultures include homeopathic medicine, naturopathic medicine, anthroposophic medicine and neural therapy. Examples of systems that have developed in non-Western cultures include Ayurveda, traditional Chinese and Tibetan medicine. Acupuncture, originally a part of traditional Chinese medicine, has evolved to a system in its own right, and is practised worldwide.

- **Biologically Based Therapies**

Biologically based therapies in CAM use substances found in nature, such as herbs, mineral and animal products, foods, and vitamins (orthomolecular medicine).

- **Manipulative and Body-Based Methods**

Manipulative and body-based methods in CAM are based on manipulation and/or movement of one or more parts of the body. Some examples include chiropractic, kinesiology or osteopathic manipulation.