Title page:

Legal status and regulation of CAM in Europe

Rechtlicher Status und Regulierung von CAM in Europa

Short title: **Legal status and regulation of CAM in Europe**

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Abstract

Objective: The study aims to: Review in 27 EU member states and 12 associated states and at the EU/EEA level the legal and regulatory status of CAM.

Methods: Contact was established with national Ministries of Health, Law or Education, members of national and European CAM associations, and CAMbrella partners. Literature search was performed in governmental, scientific/non-scientific websites as well as the web sites/databases EUROPA and EUR-lex to identify documents describing national CAM regulation and official EU law documents.

Results: The 39 nations have all structured legislation and regulation differently. Seventeen have a general CAM legislation, 11 of these a specific CAM law, and 6 have sections on CAM included in their general health care laws. Some countries only regulate specific CAM treatments. CAM medicinal products are subject to the same market authorization procedures as other medicinal products with the possible exception of documentation of efficacy. The Directives, Regulations and Resolutions in the European Union (EU) that may influence the professional practice of CAM will also affect the conditions under which patients are receiving CAM treatment(s) in Europe.

Conclusion: There is an extraordinary diversity with regard to the regulation of CAM practice, but not CAM medicinal products. This will influence patients, practitioners and researchers when crossing European borders. Voluntary harmonization is possible

within current legislation. Individual states within culturally similar regions should harmonize their CAM legislation and regulation. This can probably safeguard against inadequately justified over- or underregulation at the national level.

Ziel: Ziel der Studie war es, den rechtlichen und regulatorischen Status der Komplementärmedizin (CAM) in den 27 EU-Mitgliedsstaaten und 12 assoziierten Staaten auf EU-/ EWR-Ebene zu erfassen.

Methoden: Zunächst wurden Kontakte zu den nationalen Ministerien für Gesundheit, Recht, oder Bildung, sowie zu nationalen und europäischen Verbänden im CAM Bereich und den CAMbrella Partnern geknüpft und etabliert. Um Dokumente zu identifizieren, die die nationale CAM Regulierung sowie die offizielle EU-Gesetzgebung reflektieren, wurden Literaturrecherchen in staatlichen, wissenschaftlichen / nichtwissenschaftlichen Websites, sowie den Web-Sites / Datenbanken EUROPA und EUR-Lex durchgeführt.

Ergebnisse: Alle 39 Staaten verfügen über eine strukturierte Gesetzgebung zu CAM, die aber jeweils unterschiedlich ist. 17 verfügen über eine allgemeine Gesetzgebung zu CAM, bei 11 von diesen liegt ein spezifisches CAM-Gesetz vor, während 6 Staaten CAM spezifische Abschnitte im Rahmen ihrer allgemeinen Gesetzgebung zur Gesundheitsversorgung aufweisen. Einige Länder regeln nur bestimmte CAM-Therapien. CAM-Arzneimittel unterliegen den gleichen Zulassungsverfahren wie andere Arzneimittel, mit der möglichen Ausnahme der Dokumentation der Wirksamkeit. Die Richtlinien, Verordnungen und Beschlüsse in der Europäischen Union (EU), die die berufliche Praxis der CAM Anwendung beeinflussen, wirken sich auch auf

die rechtlichen Bedingungen aus, unter denen Patienten in Europa eine CAM-Behandlung erhalten.

Fazit: Die Vielfalt im Hinblick auf die Regulierung der CAM-Praxis ist außerordentlich hoch, dasselbe gilt jedoch nicht für CAM-Arzneimittel. Diese Tatsache beeinflusst Patienten, Anwender und Wissenschaftler beim Überschreiten europäischen Grenzen. Eine freiwillige Harmonisierung ist jedoch im Rahmen der derzeitigen Gesetzgebung möglich. Staaten in kulturell ähnlichen Regionen sollten daher ihre CAM-Gesetzgebung und Regulierung harmonisieren. Ein solches Vorgehen kann möglicherweise einer unangemessenen Über- oder Unterregulation auf nationaler Ebene vorbeugen.

Background

The European Parliament (1) and The Parliamentary Assembly of the Council of Europe (2) have both passed resolutions recommending a stronger harmonization of, what they call, non-conventional medicine in Europe.

The EU has, however, repeatedly confirmed that it is up to each member state to organize and regulate their health care system, and this will, of course, also apply to complementary and alternative medicine (CAM). Despite this confirmation, the recent Patients' rights in cross-border healthcare Directive 2011/24/EU (3) together with other Directives indirectly encourage some degree of harmonization. CAM professions can be registered in the European Commission database of regulated professions, and patients will probably have certain rights according to the Cross-border Healthcare Directive. The EU has also passed directives regulating medicinal products that also cover CAM medicinal products (4-6).

Previous studies on the European situation with regard to how CAM is regulated (7-9) have shown a diverse pattern. Reports from key CAM stakeholders have indicated that the regulatory situation has changed, and the CAMbrella consortium has therefore seen it as important to establish the current status in order to best prepare a roadmap for CAM research in Europe.

The aims of this study were to:

1. Review in 27 EU member states and 12 associated states:
    - The legal and regulatory status of CAM.
    - The governmental supervision of CAM practices.

- The reimbursement status of CAM practices.

2. Review at EU/EEA level:
   - The status of EU/EEA-wide regulation of herbal and homeopathic medicinal products.
3. Review and describe in all 27 EU member states and 12 associated states:
   - The extent of country-specific market authorization of herbal and homeopathic medicinal products according to the EU directives.
4. Review at EU level:
   - The status of EU-wide regulation of CAM practices.
   - The potential obstacles for EU-wide regulation of CAM practices.

Methods

As an introduction we made a comprehensive overview of matters that may influence CAM in the European legislation. Descriptions of health issues, the legal and CAM terminology and the interaction between conventional medicine and CAM vary both in the European Union bodies and within the 39 countries included in this report. To address CAM-related legislation in the EU, we included both the EU legislation that influences the member states' national health legislation and various aspects of EU regulation of conventional medicine.

Data underlying this report were collected from the 39 countries by communicating with the Ministries of Health, Law or Education, governmental representatives, and members of national CAM associations. A search was also performed in the national web sites/databases to identify official law documents. The scientific as well as the non-scientific literature were also searched for documents and websites describing

CAM regulation in each of the 39 countries. We also collected information from European CAM associations/coalitions, CAMbrella members and stakeholders. Personal visits, including meetings with the Ministries of Health and CAM practitioners representing organizations, were made to four countries. Health authorities (if possible both legal and regulatory) were asked to verify the situation described for their specific country. Twelve common treatment modalities have been described in detail in each country. In addition a search was performed in the web sites/databases *EUROPA and EUR-lex* to identify EU official law documents. We searched specifically for information about EU Directives regarding European-wide health care-related regulation as well as regulation of herbal and homeopathic medicinal products, and their EU/EFTA/EEA implications.

A personal visit was also made to ***the European Union offices and NGO bodies in Brussels*** to establish firsthand updated information. Meetings were held with:

1. ***Counsellor for health and food safety at the Mission of Norway to the EU.***

At the Mission of Norway to the European Union we received updated information mainly on the EFTA/EEA legal connection to EU legislation and the new Patients' rights cross-border healthcare Directive 2011/24/EU (3).

2. ***The European Commission Central Library***.

Meetings with the following NGOs gave important additional CAM documents and legal system information:

- ***IVAA*** (International Federation of Anthroposophic Medical Associations).

- ***ICMART*** (International Council of Medical Acupuncture and Related Techniques) - EU Liaison Office.
- ***AESGP*** (The Association of the European Self-Medication Industry).

We received their information, documents, and viewpoints with regard to EU regulation.

We have also collected information from ***European CAM associations/coalitions and other CAMbrella stakeholders.***

This report covers 27 EU member states as well as 12 associated states. Each state is influenced by the EU legislation and has adjusted their national legislation depending on their connection to EU.

The countries' status in relation to the EU is shown in **figure 1.**

Results

Country-specific regulations

CAM treatment is in general either unregulated or regulated within the framework of the public health system. The only common factor we have found across all 39 nations is their amazing ability they have demonstrated of structuring legislation and regulation differently in every single country, no matter how small the size of the population.

Seventeen of 39 countries have a general CAM legislation, 11 of these have a specific CAM law and 6 countries have sections on CAM included in their health laws (like “Law on health care” or “Law on health professionals”). In addition to the general CAM legislation some countries have regulations on specific CAM treatments.

(Figure 2)

The CAM regulations are either very general or very detailed, and we found no more similarities between the countries that have a CAM law or general CAM legislation than between the countries with only specific CAM treatment regulations. Some of the general regulations are only a specification of what CAM is, often to be supported by additional regulations or specifications issued by the Ministry of Health or the professions’ associations. In some countries additional specifications have not been made. As an example both Norway and Hungary have a CAM law. In Norway the CAM law is general without describing in detail the treatments or practitioners, in Hungary CAM can be regarded as an integral aspect of the health care system. We found few similarities in the regulations of the specific CAM treatments between the countries, and it is challenging to find out “who are allowed to practise” the different treatments.

The twelve treatment modalities vary considerably with regard to how many countries regulate the profession or practice in some way or another. Acupuncture is regulated in 27 countries, anthroposophic medicine in 8 countries, Ayurveda in 5 countries, chiropractic in 27 countries, herbal medicine/phytotherapy in 11 countries, homeopathy in 25 countries, massage in 20 countries, naprapathy (manual therapy) in 2 countries, naturopathy in 9 countries, neural therapy in 3 countries, osteopathy in 16 countries, and finally traditional Chinese medicine in 10 countries.

As an example **figure 3** shows the regulation of homeopathy across Europe.

Switzerland has regulated homeopathy and has registered homeopath as a profession in the EU regulated professions database under “Natural health practitioner” as naturopathe/homeopath.

2 countries (Latvia, Liechtenstein) have regulations that may be seen as a regulation of a homeopathy profession. Latvia has regulated “homeopathic doctors” Liechtenstein has registered “Naturheilpraktiker with a homeopathy specialty”.

22 countries have regulated homeopathy treatment.

14 countries have no specific homeopathic treatment regulations, but general CAM or other health legislation may regulate homeopathic practices.

Table 1 “Homeopathy - Who may practise” is an example of how difficult it can be to understand the consequences of national regulation.

We have, to our best knowledge, listed whether the different categories of practitioners in each country are allowed to practise homeopathy. If only medical doctors with CAM additional education are allowed to practise, we have put “No” in the column for medical doctors. This is done in the same way for other health personnel. If the regulation (or absence of regulation) is too unclear for us we have inserted a question mark. The countries with CAM practitioners like Heilpraktiker,

Natur heilpraktiker, healer and likewise may not be correctly represented. We have decided not to introduce this table for other treatments because of the unclear situation.

Medicinal products

Medicinal products are not defined as a part of health policy, and can therefore be regulated at the EU level. The individual state within the EU/EEA area are therefore no longer free to uphold national regulation of medicinal products in violation of the following three EU directives.

1. ***Directive 2001/83/EC of the European Parliament and of the Council, of 6 November 2001*** (on the Community code relating to medicinal products for human use) (4).

2. ***Directive 2004/24/EC of the European Parliament and of the Council, of 31 March 2004*** (amending, as regards traditional herbal medicinal products, Directive 2001/83/EC on the Community code relating to medicinal products for human use 2001/83/EC) (5).

3. ***Directive 2004/27/EC of the European Parliament and of the Council of 31 March 2004*** amending Directive 2001/83/EC on the Community code relating to medicinal products for human use (Text with EEA relevance) (6).

Herbal medicinal products marketed without authorization before this legislation came into force could continue to be marketed until 30 April 2011 under transitional

measures defined in directive ***2004/24/EC*** (5). After the recent expiration of this time limit, all previously unauthorized herbal medicinal products must have market authorization according to directives ***2001/83/EC, 2004/27/EC and 2004/24/EC*** *(4,6,5)* before they can be marketed in the EU/EEA states.

Marketing authorizations for herbal and homeopathic medicinal products are mainly given at the national level, but a central procedure can be used in some cases. Herbal and homeopathic medicinal products are subject to the same application procedures as other medicinal products regarding manufacturing procedures, technical quality of the product, and all other requirements with the possible exception of documentation of efficacy. There are four administrative procedures that can be followed to obtain a market authorization for these products (Standard, Well-established use, and two Simplified registration procedures (one for homeopathic medicinal products and the other for traditional-use registration of herbal medicinal products)). The simplified registration procedures allow alternative documentation of efficacy.

Homeopathic medicinal products covered by a registration or authorization granted in accordance with national legislation on or before 31 December 1993 and herbal medicinal products already authorized in accordance with Regulation (EEC) No 2309/93 (10) or supplied in response to a bona fide unsolicited order can be marketed irrespective of the two directives. These uniform regulations aim to supply citizens with a predictable standard of all medicinal products (including herbal and homeopathic) across Europe. Several stakeholders raised concerns before the rules were implemented. The concerns focused mainly on leaving European citizens without

access to beneficial products and the establishment of unnecessary additional authorizational bureaucracy around safe products.

EU-wide regulation

The Directives, Regulations and Resolutions in the European Union (EU) and the Council of Europe that may influence the professional practice of CAM, whether practised by an authorized/licensed health care provider or by a provider without such authorization/licensing will also affect the conditions under which patients are receiving CAM treatment(s) in Europe.

We have found no direct EU legislation of CAM except for Directives concerning CAM medicinal products described above. Two Resolutions deal with non-conventional medicine:

- ***The status of "non-conventional medicine".*** *Resolution A4-0075/97* The European Parliament Resolution on how non-conventional medicine should be included more formally as a special field in the European legislation (1).

- ***A European Approach to non-conventional medicines****. Resolution 1206(1999)*

The Parliamentary Assembly of the Council of Europe Resolution on non-conventional medicine (2).

How legislation connected to "the Four Freedoms" is handled in EU/The European Economic Area (EEA) influences the individual states' national CAM legislation and legislation that impacts directly or indirectly on CAM. Of particular interest is how patients and health professionals are able to relate to diverse national CAM

regulations. European CAM practitioners have different levels of training as a basis for their practice, whether they are formally licensed or not, and patients have varying expectations depending on experiences from their home country.

Harmonization of training and regulation of non-conventional disciplines is only marginally covered in the Directive 2005/36/EC Professional Qualifications (11). In many states only doctors or other health professionals are allowed to practise CAM according to national health regulation. The EU regulated professionals database includes only a few CAM professions in some member states. We have thus found that the Resolutions on the status of non-conventional medicine from 1997 and 1999 have not been followed up with harmonized CAM training or regulation.

Discussion

Our findings demonstrate an extraordinary diversity with regard to the regulation of CAM practice across Europe. At the same time the medicinal products CAM practitioners will be prescribing or recommending are regulated uniformly across the same geographical area. This regulatory diversity will profoundly influence patients, practitioners and researchers when crossing European borders.

When **patients** cross borders in search of CAM treatment, they may encounter substantial differences in the professional background of apparently identical CAM providers who are mostly also working under completely different reimbursement systems. In post-modern Europe where patient choice in health care is seen as a core value (12), this confusing European market makes any informed treatment-seeking challenging. This heterogeneous situation influences CAM patients' rights, access and

potential safety, and constitutes a challenge to a harmonized national and European follow-up of the new Patients' rights cross-border healthcare Directive 2011/24/EU (3).

When **practitioners** cross borders they will encounter a substantial variety of CAM practice in Europe. This raises serious concerns with regard to the predictability, quality and safety of health care delivery to European citizens. When CAM professions in some countries are tightly regulated while the same professional categories in other countries are totally unregulated, an establishment of collegial common ground is very challenging.

When **researchers** cross borders they will experience that research on efficacy and effectiveness of CAM is severely hampered by the conglomerate of European regulation. Practices and practitioners are not comparable across national boundaries, and any observational or experimental study will therefore be generalizable only within a narrow national or cultural context.

The European Parliament Resolution on non-conventional medicine from 1997 (1) stated that non-conventional medicine disciplines should be clearly identified and defined. We have found few overall clear distinctions between conventional and non-conventional medicine in the EU legislation. An adequate regulation and supervision of CAM professionals and CAM therapies will require special knowledge in the CAM field to take into account the special features of this field of health care. Developing the European legislation of CAM by simply adapting the criteria of conventional medicine will probably be inadequate for regulation of the CAM field. In a similar way that CAM research needs some particular considerations compared to research on e.g.

conventional pharmaceuticals (13), the methods by which CAM is regulated must be specifically tailored to its inherent qualities.

The Patients' rights cross-border healthcare Directive (3), in particular, respects the established differences in national healthcare systems. It aims to remove obstacles to the fundamental freedoms that enable patients from one EU member state to choose to seek treatment in another EU member state. The Directive also outlines the responsibilities of EU member state health systems to cover treatments given in other member states. Regional collaboration between providers, purchasers and regulators from the different member states can ensure safe, high-quality and efficient cross-border healthcare at a regional level. Historical and cultural similarities between neighbouring countries would thus seem to potentially facilitate cross-border opportunities in the CAM area more than EU-wide Directives, Regulations and Decisions.

The most important obstacles that hinder the European Parliament Resolution call for "a process of recognizing non-conventional medicine" are the Treaties of Rome and Lisbon (14) clearly stating that the individual member state has the responsibility for "the definition of their health policy and for the organization and delivery of health services and medical care. The responsibilities of the Member States shall include the management of health services and medical care and the allocation of the resources assigned to them". This legitimizes and sustains the wide variations in CAM regulation across Europe.

Another obstacle is the unwillingness of the individual European country to voluntarily harmonize their legislation and regulation of CAM with other European states. If this had been done to a larger degree, both patients and providers would be able to benefit from both “The right to move and reside freely” Directive (15), “The Professional Qualifications” Directive (11) “The Patients’ rights cross-border healthcare Directive” (3), as well as the Services Directive (16) and the Social Security Regulation (17).

There are therefore in principle two options that can be chosen to achieve a higher degree of harmonization: legislation and regulation at the EU/EEA level or voluntary harmonization. We do not foresee EU/EEA level legislation/regulation in the foreseeable future since the EU repeatedly has upheld its position of leaving this to the individual country. Voluntary harmonization is, however, possible within current legislation. We think it is important to encourage individual states within culturally similar regions to harmonize their CAM legislation and regulation. This broader regional perspective can probably safeguard against inadequately justified over- or underregulation at the local level. The successful mutual recognition of physiotherapists across Europe shows how this can be done. Physiotherapy has a long tradition of being a recognized profession with well-established international research on the importance and effect of physiotherapy treatment. The European collaboration within the World Confederation for Physical Therapy Europe (WCPT-E) and The European Network of Physiotherapy in Higher Education (ENPHE) leads to exchange of experience and harmonized regulation, education and professional issues within the European Union and the European countries. This could be a potential template for development of harmonized regulation also of CAM professions in Europe (18).

Conflict of interest

No author has indicated any conflict of interest.

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Legends

Figure 1. The relationship of 39 countries to the European Union.

Figure 2. The status with regard to CAM general legislation in 39 European countries.

Figure 3. Homeopathy regulation in 39 European countries.

Table 1. An overview of which groups that can legally practice homeopathy in 39 European countries.