

Master thesis by Solveig Wiesener

Disharmonized regulation of Complementary and Alternative Medicine (CAM) in Europe – Implications for patient safety



Master study: Risk management and societal safety

January 2013



MASTER STUDY IN RISK MANAGEMENT AND SOCIETAL SAFETY (MSAMAS-1)
Department of Media, Culture and Social Sciences (IMKS)

MASTER THESIS

SEMESTER: Autumn 2012
AUTHOR: **Solveig Wiesener**
SUPERVISORS: Deputy Director General, Geir Sverre Braut
Director, Professor, Vinjar Fønnebø

TITLE MASTER THESIS:

Summing up document:

Disharmonized regulation of Complementary and Alternative Medicine (CAM) in Europe - implications for patient safety.

Article:

Wiesener S, Falkenberg T, Hegyi G, Høk J, Roberti di Sarsina P, Fønnebø V. *Legal Status and Regulation of Complementary and Alternative Medicine in Europe*. *Forsch Komplementmed* 2012;19(Suppl.2):29-36.

Conference discussion paper:

Wiesener S, Fønnebø V. *CAM in Europe - a complex legal and regulative situation. Will harmonized EU-wide regulation strengthen CAM research and practice?* Paper presented at: An international and interdisciplinary conference, Regulation and Professionalization in Complementary and Alternative Medicine: historical perspectives and contemporary concerns; 5 May 2011; Hornton Grange, University of Birmingham, United Kingdom (UK).

KEYWORDS: Alternative medicine, Complementary medicine, Regulation, Government regulation, Legislation, European Union, Europe, Patient safety, Cross-border healthcare.

PAGES: 46 (excl. attachments)

STAVANGER: January 2013
MONTH/YEAR

1 Acknowledgements

Director, Professor Vinjar Fønnebø and head of administration Laila Salomonsen at NAFKAM, University of Tromsø (UiT), had the courage to hire me as senior adviser in the CAMbrella EU FP7 project. As the CAMbrella Work Package (WP) 2 leader, Vinjar encouraged and inspired me to build new competence and to fulfil the challenging task to find out how CAM is regulated in 39 countries in Europe. You are an optimistic, fair and strong leader Vinjar.

My supervisor, Deputy Director General at the Norwegian Board of Health Supervision, Geir Sverre Braut is a well-informed, clear and interested man. You have ideas and information that brings the discussion in the right direction. Thank you for your support and good spirit.

My colleagues in the CAMbrella project represent 12 European countries. You are nice and helpful people, and I am grateful for the project information you forwarded to me. Åsa Sohlén, Kari Riddervold and Brit J. Drageset at NAFKAM have given technical support. You are the best! Warm thanks are given to all my colleagues at NAFKAM. I must highlight the patient safety discussions with Trine Stub and Anita Salamonsen. You have given me feedback and interesting scientific discussions.

Most of all, thanks to my husband Olaf and my children Ingrid and Bjørg with their families. Your support and nice dinners have been essential to find strength to complete this interesting master project.

2 Preface

The objectives of this master thesis are to describe the status of Complementary and Alternative Medicine (CAM) regulation in Europe with a patient safety focus, and to analyse whether CAM regulation is in accordance with current theory dealing with risk governance and patient safety.

The master thesis consists of the following documents; this summing up document, the attached FoKoM article, and the attached conference discussion paper. Analyses and facts are based on the three CAMbrella EU FP7 project reports, delivered by the Work Package 2 (WP2), describing the status of CAM regulation in 39 European countries and in the EU/EFTA/EEC. I have performed all the field research and most of the analyses and report writing for the CAMbrella WP2, and I am first author of the article and the conference discussion paper. I presented the conference discussion paper at the conference in Birmingham.

The comprehensive data collection and analysis of CAM regulation and patient safety in Europe has been an interesting learning process.

January 2013, Solveig Wiesener

3 Summary

3.1 Research question and Objectives

Patient safety is a highly prioritized area within the provision of public and private health care services in both the European Union (EU) as a whole, member states, as well as in associated states. Risk governance giving preference to patient safety, includes regulation as an important management tool. Complementary and Alternative Medicine (CAM) is, in Europe, regulated either as conventional, complementary or alternative medicine, or not regulated at all. CAM regulation is, however, different in each of the 39 European countries included in the CAMbrella WP2 survey. Consequently an essential question is; ***What are the patient safety implications of the European disharmonious landscape of health regulation?***

The master thesis consists of the following documents; this summing up document, the attached FoKoM article, and the attached conference discussion paper. Analyses and facts are based on the three CAMbrella EU FP7 project reports describing the status of CAM regulation in 39 European countries and in the EU/EFTA/EEC.

The **objectives** for the research are: to describe the status of CAM regulation in Europe with a patient safety focus, to highlight international theory dealing with patient safety, especially the role of regulation, and to analyse whether CAM regulation in Europe is in accordance with current theory dealing with risk governance and patient safety.

3.2 Materials and Methods

CAM can be regulated both within and outside the national public health care systems. It was therefore necessary to perform a combined search for both conventional and CAM health care regulation in each country. Materials and methods used for data collection are: documents and web sites, meetings and personal communication, and questionnaires. A literature search to identify official law documents and regulations was performed in national web sites/databases, as well as scientific and non-scientific journals and web sites. Searches were performed in the web sites/databases EUROPA and EUR-lex to identify European Union (EU) official legal documents. Personal visits, including meetings with the Ministries of Health (MoH), CAM practitioners and CAM associations were made to selected countries, CAM conferences and EU associations.

It has been difficult to find appropriate methods to describe European CAM regulation in a uniform, European terminology where national legal traditions are understood and referred correctly.

3.3 Results and Discussion

Current risk governance and patient safety theory emphasize regulation as an important risk management instrument. We found no harmonization of, or comparable, CAM regulation between states, regions or in the EU, except for adapting legislation to EU directives on medicinal products.

The Directive 2011/24/EU on patients' rights in cross-border healthcare states that patients should be able to make informed treatment choices, and healthcare professionals are supposed to provide safe and effective treatments for European citizens. According to the FoKoM article and Birmingham conference paper, European patients may encounter substantial differences in regulation of and the professional background of apparently identical CAM providers and treatments both nationally and between countries.

The regulation of CAM is so unclear that information given to patients on treatment efficacy and, -risk factors and their resulting risk perception are sub-optimal. National health authorities seem to regulate CAM based on insufficient basic information about risk factors, and regulation is consequently not balanced between risk reduction and risk tolerance. By analysing each step of the regulation process, we should find indications of how and if harmonized national and EU regulation of CAM may ensure increased patient safety and CAM treatment quality in Europe.

Seen from a patient safety perspective, it is difficult to see a "CAM treatment security system" where both patients and authorities know the skills of the providers, and where the providers' performance of the modalities is standardized. However, we do not have research evidence to claim that CAM patients are more exposed to unsafe treatment offered by non-medical providers than treatment offered by regulated health personnel.

3.4 Conclusion and Recommendations

CAM in Europe is not regulated in accordance with current theory dealing with risk governance, risk regulation and patient safety.

European patients make their CAM treatment and provider choices based on insufficient and not trustworthy information. The diversity of European CAM providers' skills and regulation may challenge patient safety.

The above situation hampers CAM research, establishment of an efficient supervision system for health care providers, and reduces expected impacts of a governmental risk governance system on patient safety.

Health authorities in Europe should raise attention to how CAM risk governance and CAM regulation could be embodied within the regulation of national health care services.

The physiotherapy model of educational harmonization, research and modality standardization could be used as a template for the regulation of CAM treatments.

Treatment standardization, CAM terminology clarifications and provider harmonization together with CAM research, will probably strengthen the safety of CAM patients in Europe. A Directive on CAM could be developed more or less in parallel with the Directives 2011/24/EC and 2005/36/EC.

4 Table of content

1	Acknowledgements	4
2	Preface.....	4
3	Summary.....	5
3.1	Research question and Objectives.....	5
3.2	Materials and Methods.....	5
3.3	Results and Discussion	5
3.4	Conclusion and Recommendations	6
4	Table of content	7
5	List of abbreviations	10
6	List of papers	10
7	Introduction.....	11
7.1	Research question and objectives	12
8	Theory.....	13
8.1	Regulation and risk governance aspects	14
8.2	Health authority perspectives	16
8.3	EU perspective	18
9	Materials and Methods	20
9.1	Materials	20
9.2	Methods.....	23
9.2.1	Surveys.....	23
9.2.2	CAM associations.....	23
9.2.3	Literature search.....	23
9.2.4	Personal communication, visits and conferences	24
9.2.5	Questionnaires	24
9.2.6	The European Union (EU)	24
9.2.7	Translation from national language to English.....	25
9.3	Methodological considerations and challenges	25
10	Results.....	28
10.1	Patient perspective	28
10.2	Practitioner perspective	29
10.3	Chiropractic and physiotherapy regulation in 39 European countries.....	30

10.3.1	Chiropractic	30
10.3.2	Physiotherapy	31
11	Discussion	32
12	Conclusion and Recommendations	37
12.1	Conclusion	37
12.2	Recommendations	37
13	Supplementary data	38
13.1	Authors background.....	38
13.2	Time table.....	38
13.3	Collaboration and scientific network	38
13.4	The master study modules.....	38
13.5	Personverneombudet NSD.....	39
14	References	40
15	Attachments:	46
15.1	Article: Legal Status and Regulation of Complementary and Alternative Medicine in Europe.....	46
15.1.1	Confirm SW first author FW_ Ms. No. 201206004, Forschende Komplementärmedizin .pdf.....	46
15.1.2	First review Ms. No. 201206004, Forschende Komplementärmedizin .pdf .	46
15.1.3	Received version Ms. No. 201206004, Forschende Komplementärmedizin .pdf	46
15.1.4	Accepted revised version Ms. No. 201206004, Forschende Komplementärmedizin .pdf.....	46
15.1.5	Galley Proof Corrections and Reprint Order.pdf.....	46
15.2	Conference paper: CAM in Europe - a complex legal and regulative situation. Will harmonized EU-wide regulation strengthen CAM research and practice?	46
15.3	The description of each country. Template example – Romania	46
15.4	Template for country emails and telephone conferences.....	46
15.5	Template for interviews and descriptions for each country and treatment	46
15.6	Questionnaire: About the status of CAM therapies. Example: Romania	46
15.7	Questionnaire: Definitions and terminology of CAM and legal status of CAM. Example: Portugal.....	46
15.8	CAMBrella population-based literature review protocol Version 1.5.	46

List of figures

Figure 8.1 Relationship between research, national regulation and cross-border healthcare accessibility..... 13

Figure 8.2 Ortwin Renn: Figure 1.5 The ‘transparent’ model (source adapted from Millstone et al, 2004) in Risk Governance; coping with uncertainty in a complex world(3) 15

Figure 8.3 Ortwin Renn: Coping with Uncertainty in a Complex World. Figure 1.2 Levels of vertical and horizontal governance (Source: reproduced with permission from Bunting et al. 2007, p13)..... 15

Figure 8.4 C Hood et al. table 2.1 Control components and regulatory regime content and context..... 17

Figure 10.1 Chiropractic regulation in Europe 31

Figure 10.2 Physiotherapy regulation in Europe..... 32

5 List of abbreviations

CAM	Complementary and Alternative Medicine
DSB	Norwegian Directorate for Civil Protection
EC	European Commission
ECTS	European Credit Transfer and Accumulation System
EFTA	European Free Trade Association
EU	European Union
FoKoM	Forschende Komplementärmedizin - Research in Complementary Medicine (scientific journal) (reference abbreviation: Forsch Komplementmed)
FP7	Seventh Framework Programme
HiBu	Buskerud University College (Høgskolen i Buskerud)
MoH	Ministry of Health
NAFKAM	National Research Center in Complementary and Alternative Medicine
NCCAM	National Center for Complementary and Alternative Medicine
NGO	Non-governmental organization
NUSB	Nasjonalt utdanningscenter for samfunnssikkerhet og beredskap
UiS	University of Stavanger
UiT	University of Tromsø
WP	Work Package

6 List of papers

Article:

Wiesener S, Falkenberg T, Hegyi G, Hök J, Roberti di Sarsina P, Fønnebø V. Legal Status and Regulation of Complementary and Alternative Medicine in Europe. *Forsch Komplementmed*. 2012;19(Suppl.2):29-36(1).

Conference discussion paper:

Wiesener S, Fønnebø V. CAM in Europe - a complex legal and regulative situation. Will harmonized EU-wide regulation strengthen CAM research and practice? Paper presented at: An international and interdisciplinary conference, Regulation and Professionalization in Complementary and Alternative Medicine: historical perspectives and contemporary concerns; 5 May 2011; Hornton Grange, University of Birmingham, United Kingdom (UK).

7 Introduction

Patient safety is a highly prioritized area within the provision of public and private health care services in both the European Union (EU) as a whole, member states, as well as in associated states. Runciman et al. defines patient safety as *“the reduction of risk of unnecessary harm associated with healthcare to an acceptable minimum”*(2).

Risk assessment, risk evaluation and risk management, supplemented with risk communication and perception are important elements in risk governance irrespective of which societal field we analyze(3). It is essential in European risk governance of Complementary and Alternative Medicine (CAM) and patient safety, as in all societal fields, to have access to relevant knowledge and skills, and to establish a correct and updated decision platform.

Risk governance giving preference to patient safety includes regulation as an important management tool. Regulation is a comprehensive expression for legislation (acts and statutory decisions), other normative activity to enable activities or restrict and prevent undesirable activities, and governmental supervision(4, 5). (See chapter 8.1).

Regulations of importance for patient safety can cover requirements on provider education and training, provision of standardized and safe treatments, mandatory or voluntary professionals’ registers, supervision and professional title protection. Patients’ rights can cover correct information, safe treatment and provider choice, right to submit treatment claims, and reimbursement of treatment costs. (See attachment 15.5).

In light of the focus on patient safety in Europe one would expect a strong coherence between European health care policy and the regulation of health care services. CAM is, in Europe, regulated either as conventional, complementary or alternative medicine, or not regulated at all. CAM is often not included in the health care services, and, as published in the FoKoM article (1), we hardly find any governmental regulatory or supervisory systems covering both conventional health care and CAM.

The CAMbrella coordination project was funded by the 7th EU Framework Programme for Research and Technological Development (FP7) of the European Commission (EC), and was launched to improve the knowledge about CAM in Europe(6). The CAMbrella reports and the following research articles are meant to meet the information requirements of the estimated 100 million European citizens who are currently using CAM. The CAMbrella Work Package (WP) 2 report on the legal status and regulation of CAM may also impact European risk assessment on patient safety, health care regulation policy, and patients’ and providers’ risk perception.

Complementary and alternative medicine (CAM) is the most commonly used term for treatments provided together with or instead of conventional medicine. Since there is no common international definition of conventional, complementary or alternative medicine, the following two definitions were used as a framework for the data collection in the CAMbrella project.

- 1) The CAMbrella consortium presented a pragmatic definition of CAM in their final key notes pamphlet(7): ***“CAM, as utilized by European citizens, represents a variety of different medical systems and therapies based on the knowledge, skills and practices derived from theories, philosophies and experiences used to maintain and improve health, as well as to prevent, diagnose, relieve or treat physical and mental illnesses. CAM therapies are mainly used outside conventional health care, but in many countries some therapies are being adopted or adapted by conventional health care.”***
- 2) The National Center for Complementary and Alternative Medicine (NCCAM) in USA defines **CAM** as *“a group of diverse medical and health care systems, practices, and products that are not generally considered part of conventional medicine.”* **Conventional medicine** (also called Western or allopathic medicine) is *medicine as practiced by holders of M.D. (medical doctor and D.O. (doctor of osteopathic medicine) degrees and by allied health professionals, such as physical therapists, psychologists, and registered nurses.”* **“Complementary medicine”** refers to use of CAM **together with** conventional medicine, such as using acupuncture in addition to usual care to help lessen pain.” **“Alternative medicine”** refers to use of CAM **in place of** conventional medicine.” **“Integrative medicine”** combines treatments from conventional medicine and CAM for which there is some high-quality evidence of safety and effectiveness. It is also called **integrated medicine”**(8, 9).

CAM regulation and training is different in each of the 39 European countries included in the CAMbrella WP2 survey. A NAFKAM research application forwarded to the EU FP7 programme in 2012, states that

“European citizens are increasingly seeking a broader spectrum of treatment modalities complementary to conventional medicine. This includes complementary and alternative medicine (CAM), also when offered outside their national health care system. CAM treatments are regulated very differently, if at all, in EU/EFTA countries. This could i) impede the availability of cross-border healthcare utilization; ii) impose a risk to patient safety.”(10).

CAM modalities like acupuncture, anthroposophy, homeopathy, massage, naturopathy, osteopathy, and chiropractic are examples of modalities regulated as a conventional, alternative or complementary treatment in EU member states.

7.1 Research question and objectives

International and national CAM regulation is an important instrument to ensure a risk governance system safeguarding European citizens. Consequently an essential question is;

What are the patient safety implications of the European disharmonious landscape of health regulation?

Discussions and theory in this summing up paper are built on the FoKoM article “*Legal status and regulation of Complementary and Alternative Medicine in Europe*”(1), the Birmingham conference discussion paper “*CAM in Europe - a complex legal and regulative situation. Will harmonized EU-wide regulation strengthen CAM research and practice?*”(11), and empirical data collected in connection with the CAMbrella EU FP7 project(6). This document will concentrate on patient safety and risk governance theory, emphasize methodological challenges, and widen the discussion.

Objectives

The objectives for the research are:

1. To describe the status of CAM regulation in Europe with a patient safety focus.
2. To highlight international theory dealing with patient safety, especially the role of regulation.
3. To analyse whether CAM regulation in Europe is in accordance with current theory dealing with risk governance and patient safety.

8 Theory

CAM treatment in Europe is regulated as conventional, alternative or complementary treatments, or not regulated at all. This gives implications for patient safety.

Figure 8.1 shows how the relationship between research, national regulation and European cross-border healthcare(12) accessibility could be connected. The model could be used as a basis for a theoretical discussion regarding patient safety linked to CAM regulation in Europe.

The model (Figure 8.1) was developed by Fønnebø and Wiesener for the 2012 EU FP7 proposal “CAMCrossEurope” with the title “The Patients’ Rights in Cross-border Healthcare – Directive 2011/24/EU. Interactions with research when national healthcare regulation varies”(10).

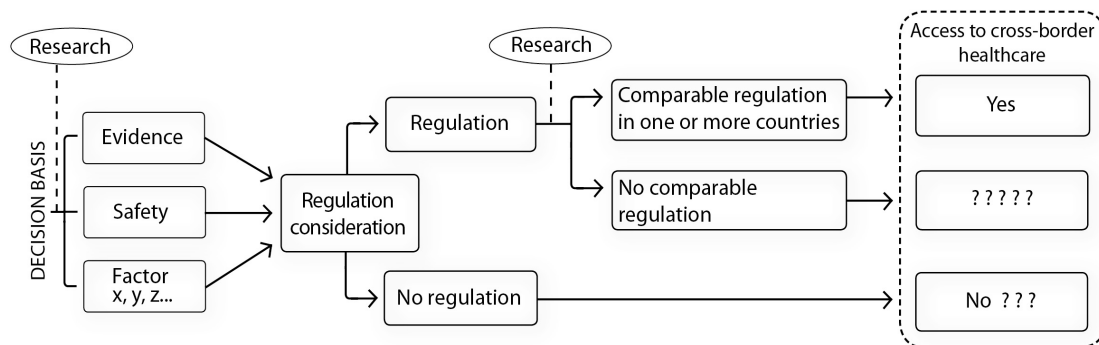


Figure 8.1 Relationship between research, national regulation and cross-border healthcare accessibility.

National legislation and regulation of health care services can be based on research and/or political, financial, traditional or cultural decisions. Important elements in these

considerations are established evidence whether and possibly how the treatments have effect and are safe, providers' skills and the organization of public health services. Patient safety aspects are included in most political decisions. Other factors like pressure from interest groups, economy, local traditions, EU and regional regulations etc. may also influence national regulation.

In 2005 The Institute of Medicine of the National Academies launched a report on CAM in USA. They stated that *"decisions about the use of specific CAM therapies should primarily depend on whether they have been shown to be safe and effective"*(13). The report's core message was:

"The committee recommends that the same principles and standards of evidence of treatment effectiveness apply to all treatments, whether currently labelled as conventional medicine or CAM. Implementing this recommendation requires that investigators use and develop as necessary common methods, measures, and standards for the generation and interpretation of evidence necessary for making decisions about the use of CAM and conventional therapies"(13).

8.1 Regulation and risk governance aspects

Regulation is seen as an important instrument to ensure safe health care practice(11). Current governmental health control systems include terms like "risk", "regulation" and "supervision", but according to Lindøe et al. (14) there is no international harmonization of the meaning of these terms. Renn (3) defines **risk** as *"a possibility that an undesirable state of reality (adverse effects) may occur as a result of natural events or human activities"*. Connected to the patient safety classification discussion, Runciman et al.(2) define a **patient safety incident** as *"an event or circumstance that could have resulted, or did result, in unnecessary harm to a patient"*. Lindøe et al.(14) conclude that governmental risk governance must be balanced between risk reduction and risk tolerance, both based on information and knowledge of risk factors.

Renn(3) describes "risk governance" as an interplay between governmental institutions, economic forces and civil society actors, such as non-governmental organizations (NGO's). Risk analysis includes risk assessment, risk management and risk communication. In addition, according to Renn(3), risk governance includes consideration of legal, institutional, social and economic contexts. Renn's "transparent model" (Figure 8.2) shows the interface between the above elements of risk assessment and management.

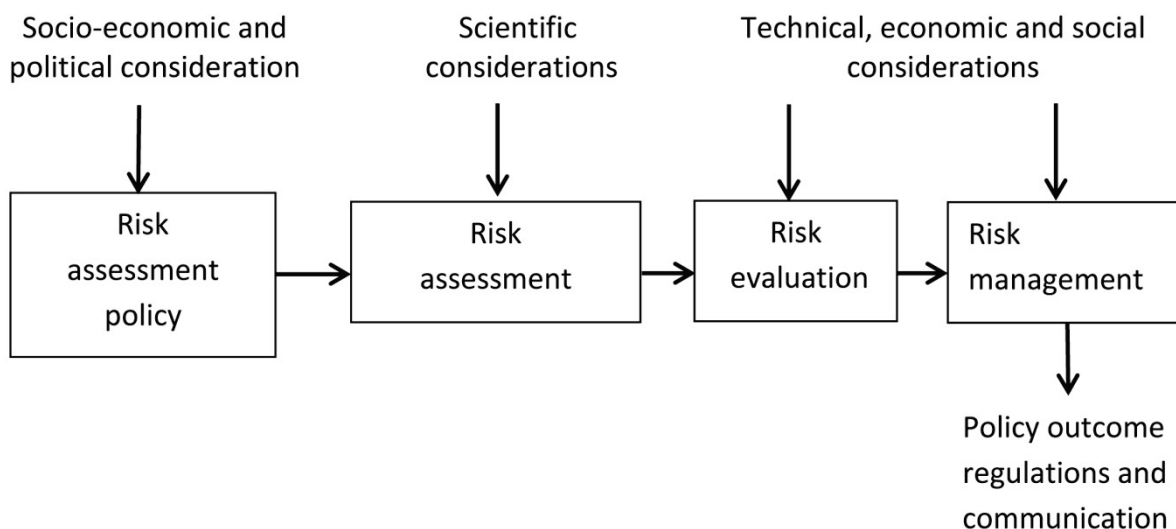


Figure 8.2 Ortwin Renn: Figure 1.5 The ‘transparent’ model (source adapted from Millstone et al, 2004) in Risk Governance; coping with uncertainty in a complex world(3)

Renn’s “transparent model” (Figure 8.2) and the “CAMCrossEurope” model (Figure 8.1) describe from different angles how risk assessment and research are important elements in governmental health regulation.

With the above figures in mind, Renn’s model on levels of vertical and horizontal governance could be used as a framework when analysing regulative and patient risk aspects of CAM practices in a national, regional, European and global perspective. Renn defines the horizontal level of governance with relevant actors and the vertical levels which execute decision-making processes within a defined geographical area (Figure 8.3)(3).

Horizontal levels

	Governments/ agencies	Industries	Science and academia	Civil society/ NGOs
Local				
Regional				
National				
Supra- national				
Global				

Vertical levels

Figure 8.3 Ortwin Renn: Coping with Uncertainty in a Complex World. Figure 1.2 Levels of vertical and horizontal governance (Source: reproduced with permission from Bunting et al. 2007, p13)

Legislation and regulation have different meanings. Legislation constitutes acts and secondary laws passed by a parliamentary/governmental body, and this legislation gives appropriate officials the authority to implement or enforce the laws(14). Primary regulations comply with rights, duties and competence, while penal provisions comply with penalties, compensations and disciplinary actions(15). According to Boe(15) international and national law are different in jurisdiction and content, and cannot easily be understood and compared by only referring to the written text. Regulation is a wider

term than legislation, used in English terminology as both acts, secondary acts and other official decisions made for restricting or enabling activities in the society(5). And to make this area even more complicated to understand, the rank order between acts, regulations and unwritten regulations may be quite clear in Norway, but can be completely different in other countries(15).

Baldwin and Cave(5) describe “regulation”:

- As a specific set of commands.
- As deliberate state influence.
- As all forms of social control or influence.

Governments’ rationale for regulation has to be in pursuit of the public interests. Access to information may protect consumers, and regulation must produce socially desirable results. For example, medical costs covered by the state instead of the patient must meet regulatory constraints to avoid unwanted excessive consumption of medical services(5).

C. Simpson states that informed patients make better healthcare decisions. Further, he claims that CAM interventions are not necessarily risk-free, but have an aura of safety, are inherently non-invasive, and “*CAM patients rarely suffer life-threatening injury at the hands of their practitioners*”(16).

According to Renn(3) important elements in risk governance are the public perceptions of risk and effective risk communication. He emphasizes that human behaviour is primarily driven by risk perception and not by facts, and points out factors like “*common-sense reasoning, personal experience, social communication and cultural traditions*”. We find these factors important when analysing why patients choose CAM treatments.

8.2 Health authority perspectives

Health authorities have regulation and supervision as risk governance tools, but regulatory bodies must also take patients’ free choice of treatments and providers into consideration(14). Governmental supervision is given authority through legislation(14), which in the 39 European countries will cover only CAM health personnel regulated by the national quality system for health services.

“To Err Is Human: Building a Safer Health System” is part of a larger project examining the quality of health care in USA(17). The report from 2000 states that a strong regulatory component is critical in order to accomplish a basic level of safety for all who use the health care system. Risk governance strategies must be implemented inside health care organizations and in their external environment to improve patient safety. External environment includes regulation and legislative actions with any form of public policy or legal influence, such as licensing or the liability system. Defined minimum levels of capability or expected performance may be monitored by an official surveillance system, and corrective actions taken to maintain the minimum levels of performance(17).

Hood et al.(18) discuss in Figure 8.4 ways of comparing risk regulation regimes. In their table 2.1 they point out three important elements in any control system; information gathering, ways of setting standards and how to change individual and organizational behaviour. They emphasize how culture and values of life influence risk regulations and setting of safety standards. They also discuss that information quality is influenced by the fact that risk regulators vary their information gathering by active, reactive or interactive methods.

	Control Components		
	Information gathering	Standard setting	Behaviour modification
Context: e.g., type and level of risk being tackled, nature of public or media attitudes, configuration of lobbies and organized interests	Example: risks individuals can assess at low cost vs risks assessable only by professionals or at high cost	Example: risks involving high stakes for organized groups vs risks with no lobby groups	Example: risks where mass public opinion resists state control vs regulation ‘with the grain’
Content: e.g., regulatory stance, organizational structure, operating conventions and regulator attitudes	Example: active vs passive information-seeking by regulators	Example: cost-benefit vs technical feasibility approaches to goal setting	Example: price signals vs command approaches to control

Figure 8.4 C Hood et al. table 2.1 Control components and regulatory regime content and context

In the book *Healthcare, Welfare and Law*(19), Molven(20) underlines the importance of a clear definition of “health personnel” and “healthcare”. He refers to the Norwegian regulation of alternative medicine as legitimizing the right to practise outside regulated health care services. He states that a similar treatment provided by regulated health personnel within established health care services is not covered by the term “alternative medicine”. According to Molven(20), regulation will contribute to patient safety through acts regulating rights and duties of health personnel, with standards of authorization and accreditation, treatment performance and skills. In the same book, Braut(21) highlights that regulation of health professionals should be based on the principle of “sound professional standards” with statute laws defining educational and training standards, good professional practice and code of ethics. Both Molven(20) and Braut(21) argue that the above principles must be expressed through legislation like a “Health personnel Act” and through the regulation of health care services in for example a “Municipal Health Care Act” and a “Specialized Health Services Act”.

Research evidence can be an important regulation tool when national and European health authorities consider regulation as shown in Figure 8.1. Recommendations from the Institute of Medicine in 2005 are to apply research methods used in conventional medicine to CAM(13).

8.3 EU perspective

The Treaties of Rome and Lisbon(22) state clearly that the individual member state has the responsibility of *“the definition of their health policy and for the organization and delivery of health services and medical care”*(1). Medicinal products are not defined as a part of health policy, and can therefore be regulated at the EU level(23). Nevertheless, EU Directives and Regulations impact national health regulations directly or indirectly. Details of EU legal systems are described in the CAMbrella report no 3: “CAM regulations in EU/EFTA/EEA(24).

Important EU directives influencing CAM regulations are:

- Directive 2004/38/EC of 29 April 2004 on the right of citizens of the Union and their family members to move and reside freely within the territory of the Member States(25).
- Regulation(EC) No 883/2004 of 29 April 2004 on the coordination of social security systems(26).
- Directive 2005/36/EC of 7 September 2005 on the recognition of professional qualifications(27).
- Directive 2011/24/EU of 9 March 2011, on the application of patients' rights in cross-border healthcare(12).
- 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(28).
- 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(29).
- 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)(30).

When introducing the Patient Rights in Cross-border Healthcare Directive(12) the Council assumes that *“safe and high-quality healthcare”* is in place when stating that there

“is a set of operating principles that are shared by health systems throughout the Union. Those operating principles are necessary to ensure patients’ trust in cross-border healthcare, which is necessary for achieving patient mobility as well as a high level of health protection”.

Conventional healthcare is regulated quite similarly across Europe, and core health professionals are defined as "Sectorial professions" benefiting from automatic recognition on the basis of harmonization of minimum training conditions (doctors, nurses, midwives, pharmacists and dentists)(27).

A profession is considered regulated when access to it and the exercise of it are subject to the acquisition of a specific professional qualification, and an important legal basis for free movement of professionals in Europe is the Directive 2005/36/EC on the recognition of professional qualifications(24, 27). Even if health professionals to an extent are regulated by EU law, national legislation in the home state or the state of affiliation is most important when professionals cross borders in Europe(31).

The European Commission database of regulated professions in the EU is covered by Directive 2005/36/EC(27). Chapter I of Title III of the directive sets out the general system for the recognition of documentation of training for the purpose of establishment in the host country(32).

“The database includes among others the professions falling under the “General System” of mutual recognition of professional qualifications and the “Sectorial professions” benefiting from automatic recognition on the basis of harmonization of minimum training conditions: doctors, nurses, midwives, pharmacists, dentists, veterinary surgeons and architects”(32).

Fisher stated in 1994 that a direct comparison of practitioners between countries, even within the European Union, are impossible because of varying legal situations(33).

Disharmonized EU-legislation was emphasized by Wiesener and Fønnebø(11) when stating that *“The established monitoring systems with regard to adverse reactions is mainly tailored to pharmaceutical drugs, and CAM supplements are therefore monitored for safety in a very rudimentary way”*. Fønnebø et al.(34) suggested a five-phase strategy for assessing CAM:

1. *Context, paradigms, philosophical understanding and utilization.*
2. *Safety status.*
3. *Comparative effectiveness.*
4. *Component efficacy.*
5. *Biological mechanisms.*

The above strategy should generate evidence relevant for clinical practice, acknowledging an unclear distinction between conventional and non-conventional medicine and absence of regulatory gatekeepers for CAM(34).

9 Materials and Methods

Data dealing with legislation and regulation of CAM and CAM medicinal products were collected from the EU and 39 European countries, of these 31 EU/EFTA member and 8 associated states¹(1, 35).

The attached FoKoM article "*Legal status and regulation of CAM in Europe*"(1), and the Birmingham conference discussion paper "*CAM in Europe - a complex legal and regulative situation. Will harmonized EU-wide regulation strengthen CAM research and practice?*"(11) are based on empirical data collected for the EU FP7-HEALTH-2009, GA No.241951- CAMbrella project(36). This work was mainly done by S Wiesener on behalf of NAFKAM and the CAMbrella Work Package 2 (WP2) group.

The three CAMbrella WP2 reports and the FoKoM article show **legislation and regulation in force**. Data used in the article are collected in the period **March 2010 to June 2012**.

We were looking for:

- General information about how each country is legally linked to the European Union and the Council of Europe.
- The legal and regulatory status of CAM and CAM practices.
- The governmental supervision of CAM practices.
- The reimbursement status of CAM practices and medicinal products.
- The regulation of the following modalities: acupuncture, anthroposophic medicine, ayurvedic medicine, chiropractic, herbal medicine/phytotherapy, homeopathy, massage, naprapathy, naturopathy, neural therapy, osteopathy, traditional Chinese medicine (TCM), other treatments if important for the specific country.
- Physiotherapy is a recognized health profession in 38 of 39 European countries, and has similarities to CAM modalities like manual therapies, osteopathy, chiropractic and others. The regulation of physiotherapy was therefore included in our survey, and also included in the discussion on how the regulation of a CAM modality may be harmonized in Europe.

9.1 Materials

Materials used for data collection are:

- Published documents.
- Web sites.
- Meetings.
- Personal communication (emails, notes).

¹ Croatia applied for EU membership in 2003. On 9 December 2011 leaders from the EU and Croatia signed the accession treaty. The country will become the 28th EU member country on 1 July 2013.

- Questionnaires.

Initially a template was made for the description of each country (attached **template example: The description of Romania**).

The following reports and book was used as a starting point for fact finding about the legal situation of CAM in Europe:

- **Stefano Maddalena**: Alternative medicines: on the way towards integration?; A comparative legal analysis in Western countries, dated 2005(37).
- **The World Health Organization (WHO)**: Legal Status of Traditional Medicine and Complementary/Alternative Medicine : A Worldwide Review [database on the Internet]. Dated 2001(38).
- **The NAFKAM/Gerd Ersdal**- EU report entitled "How are European patients safeguarded when using complementary and alternative medicine (CAM) jurisdiction, supervision and reimbursement status in the EEA area (EU and EFTA) and Switzerland" published by NAFKAM in 2005(39).
- **The World Health Organization (WHO)**: National policy on traditional medicine and regulation of herbal medicines: Report of a WHO global survey. Dated 2005(40).
- **WHO Regional Office for Europe**, on behalf of the European Observatory on Health Systems and Policies: Health Systems in Transition:The Netherlands: Health system review, published 2010(41). (Remark: one survey for each country- this is one example).

The following reports/Web pages published by CAM associations in Europe were found useful for fact-finding of CAM regulations in Europe:

- **ECHAMP** (European Coalition on Homeopathic and Anthroposophic Medicinal Products E.E.I.G): Homeopathic and Anthroposophic Medicine: Facts and Figures, published 2007(42). An updated third edition was published in 2011(43).
- **ECCH** (European Council for Classical Homeopathy): The Legal Situation for the Practice of Homeopathy in Europe; Revised Edition 2009(44). An updated edition was published in 2010 and revised in 2011(45).
- **ECH** (European Committee for Homeopathy): Web page: ECH in European Countries. Continuously updated(46).
- **CAMDOC** (Alliance ECH ECPM ICMART and IVAA): The regulatory status of Complementary and Alternative Medicine for medical doctors in Europe. Published in 2010(47).

The "**CAMBrella population-based systematic literature review protocol Version 1.5**" was developed by WP7 for use in the CAMbrella consortium (attached). The protocol was used for a systematic search in the EU/EFTA, national legal health systems and health research databases (attached).

An adjusted version of the template for the description of each country was used in telephone conferences, emails, meetings and country visits (**Template for country emails and telephone conferences**) (attached).

Meetings/CAM conferences were attended in:

- **Bologna:** CAMbrella Midterm Meeting, March 23-25, 2011.
- **Birmingham:** An international and interdisciplinary conference - 5 May 2011, Hornton Grange, University of Birmingham, UK. Regulation and Professionalization in Complementary and Alternative Medicine: historical perspectives and contemporary concerns. Conference discussion paper forwarded (attached)(11) and S Wiesener attended as keynote speaker.
- **Berlin:** 4th European Congress for Integrative Medicine and CAMbrella meeting 7 - 8 October 2011.
- **Stockholm:** CAMbrella Meeting, 9 - 11 May, 2012.
- **Tromsø:** WHO Meeting at NAFKAM. Global strategy for Traditional Medicine (TM) and analysis of WHO global questionnaires on regulation.
- **Brussels:** CAMbrella Final Conference 29 November 2012.

Personal visits were made to the following 4 countries:

- **Bosnia & Herzegovina** (Federation of Bosnia and Herzegovina (FBiH) (Banja Luka) and Republika Srpska (RS) (Sarajevo)).
- **The Czech Republic** (Prague).
- **Hungary** (Budapest).
- **Montenegro** (Podgorica and Igalo).

Meetings were arranged with the **Ministries of Health (MoH), national medicines agencies and CAM practitioners** to collect information and confirm findings. Semi-structured interviews and other personal communication followed the attached **template "Interview and description for each country and treatment"**.

The **"Questionnaire about the status of CAM therapies" ("CAMbrella" Project, EU FP7 Example: Romania)(48)** (attached) was designed and a survey organized in 2010 by the CAMbrella WP2 representative at the Ministry of Health/the Pecs Tudományegyetem – University of Pécs (Hungary) (PTE). CAM providers and MoH representatives from the following countries returned questionnaires: **Greece, the Czech Republic, Hungary, Romania, Turkey and Slovakia.**

Some information could be extracted from the CAMbrella WP1 designed questionnaire from 2010 **"Questionnaire definition and terminology of CAM and Legal status of CAM"**. **Example: Portugal (attached) (49).**

A visit was made in March 2010 to **the European Union offices and NGO bodies in Brussels**, and meetings were held with:

- **Counsellor for health and food safety at the Mission of Norway to the EU.**
- **The European Commission Central Library.**
- **IVAA** (International Federation of Anthroposophic Medical Associations) and **ICMART** (International Council of Medical Acupuncture and Related Techniques) - EU Liaison Office.
- **AESGP** (The Association of the European Self-Medication Industry).

9.2 Methods

9.2.1 Surveys

The work was initialized by a literature and web search for surveys performed on CAM legislation and regulation in the last decade (dated from 2000 – 2011). Information found in these reports and books was used as a starting point for fact finding about the legal situation of CAM in Europe.

A number of other surveys similar to those mentioned under 9.1 were reviewed. Most of them referred to the above-mentioned documents or did not add facts of interest.

9.2.2 CAM associations

We searched in web pages and databases for material published by European and national associations representing the different CAM modalities included in our survey. These associations have generated surveys, publications and web pages showing the regulatory situation of CAM in Europe. Representatives of the CAM associations forwarded published surveys, national contact information, and links to web sites and databases. Fact discussions and rechecks were done in collaboration with the CAM associations.

9.2.3 Literature search

A literature search to identify official law documents was performed in national web sites/databases, and scientific and non-scientific journals and web sites. We searched for official legal documents on the MoH and other governmental legal and official web sites in 39 countries. A search was performed for web sites representing most of the national and European CAM associations and professions included in the survey. We also performed a literature search in European CAM scientific journals, and in the EU/EFTA databases (EUROPA and EUR-lex). The CAM terminology and healthcare regulatory systems are so diverse that a systematic literature search gave few hits and limited information. A systematic literature search in EU/EFTA databases (EUROPA and EUR-lex) for regulation and legislation of CAM gave few hits, but search for specific, detailed information gave some results.

During the data collection and analysing process it also became clear that conventional health care regulation has a strong impact on CAM. The search results became more successful when regulation of conventional health care was included.

9.2.4 Personal communication, visits and conferences

Communication with the Ministries of Health, Law or Education, national medicinal agencies, other governmental representatives, members of national and European CAM associations/coalitions and CAMbrella members and stakeholders was performed with the help of emails and telephone conferences. New contacts and information were gained in meetings/CAM conferences in Europe.

Personal visits, including meetings with the Ministries of Health (MoH) and CAM practitioners were made to four countries (see 9.1). These countries were selected on the basis of a need to double-check published information and to collect information on countries where information was not easily accessible.

The CAM regulatory situation in each country is unclear. Therefore, in order to gain information from different interest groups, data was collected from bureaucrats, politicians, medical professionals and CAM providers. A few times health authorities were asked to verify the situation described for their specific country.

Interviews and other personal communication were semi-structured. Questions became more direct and specified as the work progressed, and information was compared to data collected from other sources and for other countries. In many cases data had to be rechecked with the informants.

9.2.5 Questionnaires

One questionnaire survey was organized in 2010 by the CAMbrella WP2 representative in Hungary to gain information from countries in the eastern part of Europe(48). Six countries representing both EU member states and candidate countries returned the questionnaire.

A CAMbrella WP1 designed questionnaire from 2010 included a few questions on CAM legislation(49). The answers were of low quality, and questionnaires from very few countries were forwarded to us. The information was used to give direction for further research.

A WHO Global Survey questionnaire was disseminated in 2011. It was based on the global survey *“National policy on traditional medicine and regulation of herbal medicines”* launched in 2005 (with data collected in 2001)(40). WHO denied our request to get copies of the returned questionnaires. However, in meetings with the MoH in two of the countries visited, we saw that their answers on the questionnaire and response given directly to us in the meeting differed for some of the questions. Based on information given in the WHO questionnaires we discussed these facts with the country officials.

9.2.6 The European Union (EU)

Searches were performed in the web sites/databases EUROPA and EUR-lex to identify European Union official legal documents. To address CAM-related legislation in the EU, both the EU legislation that influences the member states' national health legislation and

various aspects of EU regulation of conventional medicine were included. We searched for EU Directives and Regulations regarding CAM, and their EU/EFTA/EEA implications. Further, we searched for documents on other health issues, including legislation in progress, relevant for CAM. In addition data was collected from Decisions, News, Resolutions and relevant "Information" documents launched from the European Commission, the European Parliament and the Council of Europe.

The Mission of Norway to the European Union provided information mainly on the EFTA/EEA legal connection to EU legislation and the new Cross-border Healthcare Directive 2011/24/EU(12). The European Union Commission Library assisted in searching for documents. AESGP provided information about the EU regulation of medicinal products(24).

9.2.7 Translation from national language to English

Legislation and regulation is written in the national language in each of the 39 countries. Few of the documents have an official translation to English. Information in the national languages was either translated to English in an official version by the MOH or CAM association contacts, or native contacts helped to find the information and forwarded an English version. In some cases Google Translate gave adequate information for further search, either on web sites or by forwarding references or documents to native contacts who extracted information in English. References are given to the original documents in the original language if there is no official translation of the document. In some cases we forwarded the English version of country descriptions to national, governmental representatives and/or CAM associations and providers to be confirmed. This was a continuous quality process until the delivery of the CAMbrella reports.

9.3 Methodological considerations and challenges

It has been difficult to find appropriate methods to describe European CAM legislation in a "uniform, European legal terminology" where national legal traditions are understood and referred correctly. CAM terminology, and the interaction between conventional medicine and CAM, in regulation, health care systems and research vary widely in the 39 countries and the EU. Thus, it was necessary to make a comprehensive search for matters that could influence CAM in national and EU/EFTA legislation. The report intended to describe facts on legislation and regulation in force at the primary and secondary legal level. Since CAM can be regulated both within and outside the national public health care systems, it was necessary to perform a combined search for conventional and CAM health care regulation in each country.

Within the same country and even within the same institution informants gave a substantial diversity of answers to similar questions. It was therefore essential to communicate with representatives from different environments in the EU and the 39 European states. Most of the trustworthy information was found by using different search methods, and then compare and verify data by rechecking the information. Even

information given from the Ministries of Health (MoH) had to be rechecked. The attached *“template for interviews and descriptions for each country and treatment”*, shows the definitions used in interviews and data collection. The interview situation differed widely. In most countries it was necessary to start with a discussion and clarification on terminology and definitions of CAM before establishing facts about legislation. No national legislation were directly comparable to other countries, so information had to be confirmed repeatedly and from different angles also during the interviews. Our experiences correspond with Boe’s findings, referred to in chapter 8.1., that international law is difficult to compare and understand.

A search for surveys can be efficient and time-saving for data collection. Some of the surveys were based on questionnaires, others on combined methods. However, it was impossible to completely trust the data. CAM and regulatory definitions and terminology varied, data included or excluded differed between the studies, and regulative definitions were unlike those used in the CAMbrella project. Data collected turned out to be wrong or inaccurate, and relevant data was often missing. Legislation is an on-going process with continuous changes in most countries. The information extracted from the surveys was not updated to the situation in 2010-2012. The Stefano Maddalena book from 2005(37) is based on data collected in 1999. Most of the surveys referred to the Maddalena book or to surveys from 2005 or earlier, and most surveys referred to each other. The surveys published by the CAM associations from 2005 up to 2011 were also based on and referred to findings in surveys from before 2005. The number of countries included in each survey differed. Many of the 39 countries included in the CAMbrella work were not included in these surveys. In other cases information was missing for some countries even if they were included in the survey. References to laws and regulations turned out in many cases to be incorrect. As a consequence much of the data in the surveys were found to be too old, wrong or inaccurate. However, the data found was used for further search and was also compared to information found using other methods.

As discussed by Lindøe et al.(14) the words “regulation” and “legislation” have different meaning depending on whom you ask, and we struggled to find a way to describe facts as precisely as possible. In our work we used the word “regulation” as a comprehensive term for all forms of official regulation and acts, while the word “legislation” is used when referring directly to laws.

The “fact” situation in each country was described by including every official document at the primary and secondary legal level containing anything about CAM or the CAM modalities included in our survey. Each country was described by using one template, but national descriptions and references were developed in a narrative form. In the FoKoM article we referred to data that we found comparable. However, figures 3 and 4 on Homeopathy in the article(1) show how difficult it is to find a valid method to compare CAM regulation in Europe.

Questionnaires are efficient for collecting comparable data from many informants. However, it was difficult to develop a questionnaire design that ensured trustworthy answers. We compared questionnaires returned to WHO in their “2012 questionnaire” with information provided to us on the same questions. We found several discrepancies when comparing information collected by these two methods.

Systems and the cultural tradition of governmental regulation in states from the Eastern Europe differ in many aspects to the “old” European way of regulating healthcare services and providers. It was expected that the questionnaire developed only for use in the Eastern countries would ensure correct and comparable data. However, the questionnaire answers were not valid due to language challenges, different CAM terminology or regulatory differences between the states. The information was therefore only used for further research. Hardly any of the answers in the WP1 questionnaire were valid.

Based on our experiences when studying the above questionnaires we found it of no value to develop a specific “CAMbrella” questionnaire for fact-finding of CAM regulation in the European countries. This method was therefore not used for further data collection.

Legal documents on CAM regulation are usually not found in research databases, and most CAM research articles discuss aspects of CAM with few direct references to updated national legislation. Common expressions found were “osteopathy is regulated in NN country”, “only doctors may treat patients”, “health personnel may provide acupuncture”, or as found in the Criminal law in Croatia: “*Whoever, lacking prescribed, professional qualifications, medically treats another or renders medical aid to such a person shall be punished by-..*”. These expressions gave a starting point for further search on legal documents describing CAM treatments or providers.

Since most legislation is written in the respective national languages, meanings and nuances may be lost in the translation process. For most of the countries the English phrasing of the legal and regulatory situation can be challenging. The legal regulation of CAM is often a controversial political matter, and one country preferred to present their own written description of their CAM situation.

The CAMbrella advisory board represents European CAM associations. They used their comprehensive network in Europe to double-check information.

It has been challenging to extract comparable data from the 3 CAMbrella reports for use in the attached FoKoM article(1). To my best knowledge data described in the article is trustworthy and updated. However, when describing the legal situation for CAM in Europe, one must be aware of and, if possible, highlight the definitions and terminology in use, and clearly describe which data that have been included and excluded in the discussions.

10 Results

Legal systems regulating national health care services vary between the 39 European countries, and we found no two countries where national legislation or regulation of CAM was comparable. Even when CAM was regulated, the question “who are allowed to practise NN treatment?” was difficult to answer. An example of how difficult such interpretations could be is shown in the FoKoM article Fig. 4. “An overview of groups that can legally practice homeopathy in 39 European countries”(1).

At the Birmingham conference in 2011(11) we presented that we had found two main approaches to CAM regulation; countries where all practice of CAM is regulated in some way or another, and countries that do not regulate the field at all or only regulate some of the CAM treatments. The distinction between those two approaches became more diffuse when we gathered more detailed information from each country, so in subsequent presentations we found more suitable ways of describing the status of CAM regulation in Europe.

We found that the 12 new EU member states admitted in 2004 and 2007, as well as the 8 candidate states(1, 35) had changed their health legislation to adjust to EU membership or application. However, we found no harmonization in legislation between states, regions or in the EU, except for adapting legislation to EU directives on medicinal products.

10.1 Patient perspective

We found the regulation of CAM in Europe so unclear that the information given to patients on treatment efficacy, risk factors and their following risk perception cannot be optimal.

The task of CAMbrella WP3 was to identify the needs and attitudes of European citizens with regard to CAM. They found that *“Citizens call for impartial, reliable and trustworthy information to support informed decision-making, and some citizens wish for greater support and involvement of biomedical healthcare professionals in facilitating their healthcare choices.”*(50).

Reimbursement of CAM treatment is mostly obtained only if provided within the conventional healthcare services, by a regulated health professional or if the CAM treatment is regulated. In most countries reimbursement is covered only if the patient has private insurance. Patients may receive CAM in one country, with treatment expenses reimbursed in their home country. However, the amount of expenses covered for each treatment depends on how CAM is regulated in both countries.

A successful implementation of the directive on patients' rights in cross-border healthcare(12), makes it imperative to have an appropriate overview of the national CAM regulation in the EU member states. According to the directive patients should be able to make informed treatment choices and healthcare professionals are supposed to provide

safe and effective treatments for European citizens. According to the FoKoM article(1) and Birmingham conference paper(11) European patients may encounter substantial differences in regulation of and the professional background of apparently identical CAM providers and treatments both nationally and between countries(1). *“This heterogeneous situation influences CAM patients’ rights, access and potential safety”*(1), and patients seeking these treatments cannot make use of their cross-border rights if their own (state of affiliation) and the other country (member state of treatment) have not regulated the treatment similarly(10).

10.2 Practitioner perspective

Legislation on health professionals was found in all the countries included in the CAMbrella WP2 survey. We found acts like “Health professionals Act” and “Public Health Care Services Act” (named slightly different in each country). Requirement to practise according to “sound professional standards” was expressed with various terms, but was found in most of the acts and regulations. CAM professionals were included in the acts in some countries and not at all in others. Each country regulates health professionals and CAM providers differently, and we found no comparable list of health professions included in these acts. Consequently, in the reports we described if and how the respective CAM profession was regulated.

When reviewing the regulation of health professionals we looked for standards for educational level and training (including ECTS standards), registration in the EU health professionals’ database, protected title, statutory or voluntary registers, and code of ethics, licences and authorizations. Health professions and treatments were regulated by national general or specific law, or regulation was delegated to associations or government offices.

CAM is in some European countries provided by regulated healthcare professionals and thereby clearly covered by the Directive 2011/24/EC on the application of patients' rights in cross-border healthcare(12) and the Directive 2005/36/EC on the recognition of professional qualifications(27). The same CAM practice unregulated or regulated with different requirements in another country would not be covered by these directives(36).

Few of the EU member states have CAM professions registered in the EU regulated professions database (see examples in Figure 10.1, Figure 10.2). We have not found that harmonization of training for CAM professionals constitutes a special focus in the Directive 2005/36/EC on professional qualifications(27) or in national health regulation. Several member states only permit doctors or other health professionals to practise CAM. Other member states have introduced legislation regulating CAM practice by non-licensed health practitioners.

European countries have established national health supervision systems for regulated health professionals (doctors, nurses, midwives etc.), but this system will only apply to CAM practitioners regulated as health personnel(11). In some countries the follow-up of

CAM regulation has been delegated to medical or CAM associations. This system could cover the authorization of CAM providers, education and training, licences and statutory or voluntary registers. (For example Brønnøysundregistret in Norway(51, 52)). In a few countries with CAM regulation, provider supervision may be performed through those associations.

10.3 Chiropractic and physiotherapy regulation in 39 European countries

10.3.1 Chiropractic

Chiropractic is a treatment and profession that, if regulated at all, is regulated in Europe as conventional, alternative or complementary. Chiropractor is recognized and regulated as a conventional health profession in 16 of the 39 countries. 10 of these countries have also registered chiropractor in the EU regulated professions database. Even so, educational and professional regulation differs between these countries. In 10 countries there is regulation on chiropractic treatment, but not a regulated profession called chiropractor.

In 13 countries we found no specific regulation of chiropractic, but the treatment may be regulated through CAM general legislation or conventional health legislation. Some countries regulate chiropractic and similar therapies as “manual therapies”, and we found regulation describing that other professionals may use chiropractic treatment methods, for example physiotherapists.

We found few comparable European regulation standards for the protection of the chiropractic title, curriculum and training, professional exercise or code of ethics. From 2012 the European chiropractors’ union together with the European committee for standardization is preparing European standard requirements and recommendations for healthcare services provided by chiropractors.

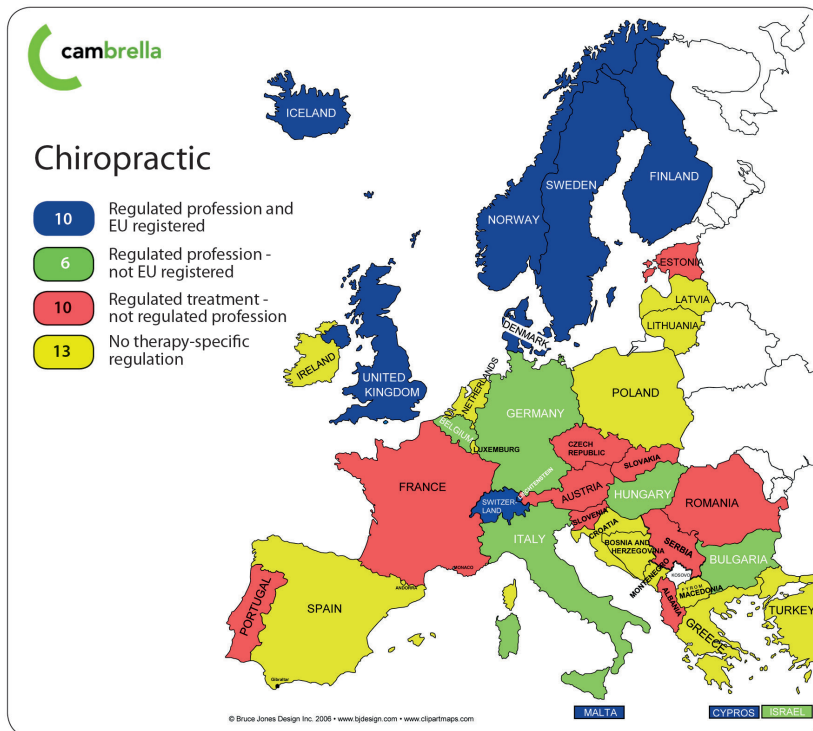


Figure 10.1 Chiropractic regulation in Europe

10.3.2 Physiotherapy

Physiotherapy is recognized as a conventional regulated health profession in 38 of the 39 countries we have described, and 29 of 31 EU/EEA members have registered the profession in the EU regulated professions’ database (Figure 10.2). Physiotherapy has been harmonized according to the “General system” of mutual recognition of professional qualifications according to the professionals directive(27). With collaboration through The World Confederation for Physical Therapy (WCPT) Europe, together with the European Physiotherapy Associations, physiotherapists across Europe hold the same professional standards, and patients are ensured that they will encounter professionals with similar background and experience.

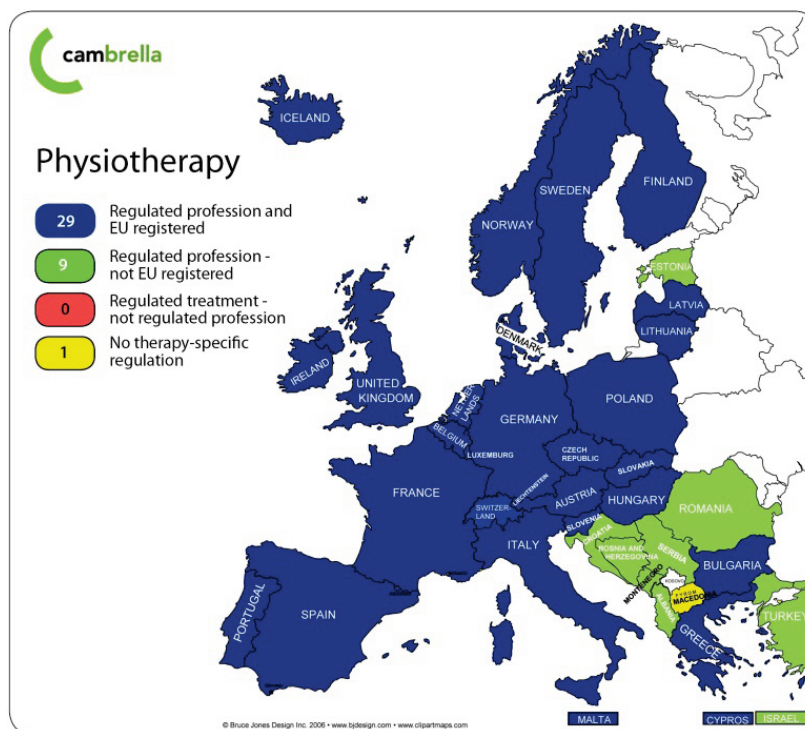


Figure 10.2 Physiotherapy regulation in Europe

11 Discussion

We found it challenging to establish a correct, comparable system for the description of CAM regulation in Europe. None of the 39 European countries' health care legislation or regulation was comparable directly with other countries since CAM, conventional treatments, providers, health professions, education, supervision, reimbursement, authorization and licences are defined and regulated differently. It was not possible to use one specific definition of CAM or "regulation" when gathering data from the 39 countries. We solved those challenges by describing facts found for each country showing how they had defined and regulated CAM in general and each of the 13 chosen treatments.

Consequences of disharmonized CAM regulations for patients, providers and research are discussed in the FoKoM article(1) and in the conference paper(11). An important question is if and how more harmonized regulation of CAM in Europe will influence patient safety. Are adverse events more common in CAM treatment than in conventional treatment provided by regulated health personnel? As stated by Stub et al.(53) "The Medical Homeopaths used the view of both professions and always looked for red flag situations in the consultation room", and further her informants expressed that "A more comprehensive toolkit gave the medical homeopaths a feeling of professionalism", and "They combined knowledge from two treatment systems which may have advantages for the patient".

The homeopath example leads to several questions. Medical homeopaths have both a medical education and homeopathic training. It seems reasonable to claim that this will

strengthen their homeopathic practice and thereby the patient safety. But what happens when the medical doctor has less homeopathic training? Will he/she provide a safer treatment than a non-medical homeopath with comprehensive homeopathic training? Perhaps the treatment is safe, but what is the quality of the homeopathic treatment? On the other hand, the non-medical homeopath will probably provide a safe homeopathic treatment for most of the patients, but we do not know if his/her medical competence will cope with adverse events in the same way as a medically trained provider.

Regulation ensuring that homeopaths have a minimum level of medical training may meet some of the above challenges. For example, to be a member of Norske Homeopaters Landsforbund (NHL) and registered in The Brønnøysund Register you need 120 ECTS credits of medical training added to the homeopathic training. If these training standards were equal all over Europe, all homeopaths would probably know when to stop their own treatment and refer to conventional treatment. Similar thinking is possible for all CAM modalities.

The decision platform for CAM regulation in Europe is unclear. Regulation of conventional health care modalities and providers seems mainly to be based on standardization and research, and conventional health care services in the European countries are to a great extent comparable, even if the legislative expression of the normative fundament may vary considerably. The national governmental decision basis and consequences for European CAM regulation both need to be analysed to fulfil the EU Commission's intention *"to ensure patients' trust in cross-border healthcare, which is necessary for achieving patient mobility as well as a high level of health protection"*(12). The "CAMCrossEurope" model (Figure 8.1) could be a template for this work. If the model in Figure 8.1 is valid, by analysing each step of the regulation process, we should find indications how and if harmonized national and EU regulation on CAM may ensure increased patient safety and ensure CAM treatment quality in Europe.

It is difficult to describe the connection between patient safety and legal regulation of complementary and alternative medicine (CAM) in Europe. The European and national heterogeneous regulation of CAM providers and treatments may be unsafe for the patients, but many consider CAM as mostly "well-being" treatments with few patient safety challenges. It is, however, a problem that European citizens do not make their treatment choices on an informed platform, where they can balance risk facts and their own risk perception with risk tolerance. National health authorities seem to regulate CAM based on insufficient basic information about risk factors, and regulation is consequently not balanced between risk reduction and risk tolerance. By this absence of regulation standards, Renn's (3) recommendations for efficient risk governance and management can hardly be followed.

The C Hood et al. model(18) (Figure 8.4) underlines the importance of comparable information gathering in risk regulation. As discussed in the material and methods

chapter, as well as shown in results, this element is a substantial challenge both in national and international CAM regulation. As concluded in the CAMbrella WP3 report(50) patients make their decisions in an unreliable and not trustworthy environment which makes it impossible to fulfil the Cross-border Directive(12) intentions that patients shall be able to make informed treatment choices when crossing borders in Europe.

Even within many European countries it is difficult for patients, providers and authorities to make informed decisions. Further, many CAM providers are not regulated as health personnel, and consequently not covered by governmental supervision. This limits patients' compensation claim rights, and the possibility of complaints and reimbursement of treatment costs.

In Europe there are more than 150.000 registered medical doctors with an additional CAM certification and more than 180.000 registered and certified non-medical CAM practitioners - however, regulation of and education in CAM is different in all the 39 European countries. Reflecting this fact, Professor Wolfgang Weidenhammer said at the CAMbrella final conference in Brussels in November 2012: *"Health professionals must give safety and security to their patients and clients. The current EU regulation and education chaos for CAM provision makes this an impossible task."*(54). The European governments' rationale for regulation or non-regulation of CAM is diffuse, and it seems like "the public interests" mentioned by Baldwin and Cave(5) is not clearly given priority.

The CAMbrella WP2 results are supported by the CAMbrella WP5 findings. According to their conclusion we find that Fisher's statement from 1994(33) is still valid in 2012;

"CAM provision in the EU is maintained by approximately 305,000 registered medical doctors and non-medical practitioners, with a huge variability in its national regulatory management, which makes any direct comparison across the EU almost impossible. Harmonisation of legal status, teaching and certification of expertise for therapists would be of enormous value and should be developed."(55).

It is difficult to describe the legal status and regulation of CAM in Europe when there are no common definitions and terminology of conventional, complementary and alternative medicine. More important, the differences in CAM regulation make it challenging to ensure safe practice of CAM across boundaries in the EU/EEA area(11). A successful implementation of the directive 2011/24/EU on patients' rights in cross-border healthcare(12), makes it imperative to generate a correct overview of national CAM regulation in the EU member states. European health authorities need to discuss how the safety of CAM patients can be safeguarded under the current regulatory system(11).

Complementing national legislation, Directive 2005/36/EC(27) supports harmonized regulation of health personnel in all EU member states, and the principle of sound

professional standards for health professionals is to a great extent harmonized for regulated professions. However, hardly any of the CAM professions are included in those regulations, so practitioners and patients - crossing borders encounter a substantial variety of CAM practice and practitioners' competence in Europe. As stated in the article, *"this raises serious concerns with regard to the predictability, quality and safety of health care delivery to European citizens"*(1). With the mutual recognition of medical doctors within the EU, some physicians could be well qualified for CAM treatments, while others, immigrating from countries with no mandatory or voluntary training in CAM in their medical curriculum, may be unqualified to practice CAM modalities. Safety aspects will accordingly be based on unclear standards of skills and medical knowledge for CAM practitioners in Europe.

If we look into the regulation of chiropractic treatment in Europe it is natural to ask if there is more evidence-based research available in countries where chiropractic is regulated compared to countries with no regulation of chiropractic providers or treatment? Also, is it safer to receive chiropractic treatment in countries with regulation than in countries with no such regulation? Compared to the physiotherapy and homeopathy discussion it is fair to argue that harmonized standards with regard to medical and CAM education and training, combined with research, will ensure a higher level of safety for patients receiving CAM treatments.

The successful development processes towards harmonized regulation and today's mutual recognition of physiotherapists across Europe could be a potential framework for standardization of other CAM professions and treatments like chiropractic, massage, osteopathy, naprapathy and others.

Directive 2011/24/EU on the application of patients' rights in cross-border healthcare(12), stipulates that *"Member States should facilitate cooperation between healthcare providers, purchasers and regulators of different Member States at national, regional or local level in order to ensure safe, high-quality and efficient cross-border healthcare"*(12, 31). When analysing CAM regulation in 39 European countries the FoKoM article concludes that it is important to encourage individual states within culturally similar regions to harmonize their CAM regulation(1).

The fulfilment of the Institute of Medicine statement from 2005 about common evidence standards for CAM and conventional medicine will meet many challenges(13). Statements like "CAM is mostly well-being treatment" and others claiming that "CAM is safe and have few adverse effects" will probably influence how health authorities regulate CAM and patients' choice of treatment. It seems like patients want to choose freely among conventional, complementary and alternative medicine, and CAM treatment is in many cases chosen when conventional medicine does not fulfil expected and wanted treatment effects.

European cross-border research on efficacy and effectiveness of CAM is severely hampered by the conglomerate of European regulation(1). A structured systematic literature review by the CAMbrella Deliverable 10: “ Roadmap for future research” in 2012, supports the Institute of Medicine 2005 report(13) and states that “*Most authors vote for the use of commonly accepted research methods to evaluate CAM*”(56). Both reports point to severe methodological challenges for CAM research, but show a consensus that both qualitative and quantitative methods are valuable and that “*a mixed methods approach is the most suitable for gathering conclusive knowledge about CAM.*”(56). The CAMbrella WP4 reviewing CAM prevalence in Europa states that “*A consistent definition of CAM, a core set of CAMs with country-specific variations and a standardized reporting strategy to enhance the accuracy of data pooling would improve reporting quality*”(57). As discussed in chapter 9 (Materials and Methods) the methodological challenges found in all these CAMbrella articles are also experienced when collecting data for the WP2 report and for the WP2 FoKoM article.

Supervision of CAM professionals is hampered by absence of legislation in the European countries. Consequently regulated health care personnel providing CAM, like doctors, nurses, midwives and others, are supervised, while non-medical (not regulated) providers of CAM will be excepted from the governmental supervision system. On the other hand, CAM training could be more comprehensive for providers not holding a regulated health profession. In some countries CAM treatment is restricted to medical doctors, in others there are no official provider restrictions in national health regulation. The official control system includes or excludes CAM providers depending on regulation of other professional skills than those needed for the specific CAM treatment. Unregulated CAM providers can be prosecuted according to Criminal Law.

Hood et al. (18) underline the importance of comparable standards and information in risk regulation. We found few standards in European CAM regulation, and governmental risk assessment for CAM is hardly based on informed, comparable safety information. However, the European health professionals’ associations have started many processes to achieve more professional standardization. Good examples are the associations representing physiotherapists, chiropractors and homeopaths. Patient safety and CAM risk governance could be improved by supporting the CAM associations with international standards for CAM health care services and CAM training developed by health authorities in Europe.

Seen from a patient safety perspective, being aware of the CAM regulation found in 39 countries, it is difficult to see a “CAM treatment security system” where both patients and authorities know the skills of the providers, and where the providers’ performance and the content of the modalities is standardized. However, we do not have research evidence in our project to claim that CAM patients are more exposed to unsafe treatment offered by non-medical providers than treatment offered by regulated health personnel.

To ensure safe health care practice, current risk governance and patient safety theory emphasize the importance of legislation and regulation as risk management instruments. A review of CAM regulation in 39 European countries, with a patient safety focus, shows that European CAM regulation is disharmonious and unclear. With this background health authorities in Europe should raise attention to how CAM risk governance and CAM regulation could be embodied within the regulation of national health care services.

12 Conclusion and Recommendations

12.1 Conclusion

CAM in Europe is not regulated in accordance with current theory dealing with risk governance, risk regulation and patient safety. A review of the status of CAM regulation in 39 European countries, with a patient safety focus, shows that European CAM regulation is diverse and unclear. Consequently, it is fair to claim that the disharmonious landscape of CAM regulation in itself may impact patient safety.

European patients make their CAM treatment and provider choices based on insufficient and not trustworthy information. CAM terminology is not uniformly defined and treatment modalities are not standardized.

CAM professionals can be medical doctors or other health professionals, with or without CAM training, or non-medical CAM providers with long or short CAM training. We found few mandatory or standardized CAM training programmes and professionals' registers. This diversity of European CAM providers' skills and regulation may challenge patient safety.

The above situation hampers CAM research, establishment of an efficient supervision system for health care providers, and reduces expected impacts of a governmental risk governance system on patient safety.

12.2 Recommendations

Regulation of CAM could be embodied within a risk governance system covering conventional, alternative and complementary health care services. Treatment standardization, CAM terminology clarifications and provider harmonization together with CAM research, will probably strengthen the safety of CAM patients in Europe. A Directive on CAM could be developed more or less in parallel with the Directives 2011/24/EC(12) and 2005/36/EC(27).

The physiotherapy model of educational harmonization, research and modality standardization could be used as a template for the regulation of other CAM treatments.

Development towards European harmonized regulation of CAM would probably give patients, health care providers, researchers and governmental authorities a similar standardized, informed and safe decision platform.

13 Supplementary data

13.1 Authors background

I have a position as senior adviser at NAFKAM (The National Research Center in Complementary and Alternative Medicine), Faculty of Medicine, the University of Tromsø, Norway. The last 3 years I have been connected to the European Union (EU) - CAMbrella project (1), and the main work for Work Package 2 (WP2) "Legal status and regulations" has been carried out by me. The CAMbrella project consortium consists of 16 partner institutions from 12 European countries. Empirical data was collected from 39 countries and the EU/EFTA/EEA. The final delivery of 3 reports (with me as the first author of two) was forwarded to the EU on November 29, 2012. Two reports describe national regulation of CAM in 39 countries and in the EU/EFTA, and the third report describes regulation of CAM medicinal products in Europe. The empirical data will be used for further research, including the FoKoM article(1) and this summing up document for the master thesis.

13.2 Time table

Data has been collected from May 2010 - May 2012. Quality check and updates were carried out during autumn 2012 until final delivery of the CAMbrella EU project late November 2012.

13.3 Collaboration and scientific network

I collaborate with researchers at NAFKAM and with the CAMbrella network in Europe. Patient safety is included in the strategy plans for future research at NAFKAM. NAFKAM is a collaborating centre with the World Health Organization (WHO).

13.4 The master study modules

This master thesis is the final module of the Master program: "Masterstudier i samfunnssikkerhet"- a collaboration study program between the Buskerud University College (HiBu), the University of Stavanger (UiS) and Nasjonalt utdanningscenter for samfunnssikkerhet og beredskap (NUSB) placed under the Norwegian Directorate for Civil Protection (DSB). In addition to this thesis, the master program has included the following study modules and my exam deliverables (available only in Norwegian):

- **Infrastructure and vulnerability** (UiS MTS230): Hvorfor er distribusjonsdelen av kraftforsyningen i Norge ikke forberedt på å møte et fremtidig endret klima? (Why is the distribution of Norwegian power supply not prepared to meet future climate changes?).
- **Risk based management** (UiS MTS140): Sort gull til besvær! Økt skipstrafikk - økt risiko? (Black Gold Challenges! Increased shipping – increased risk?).
- **Risk and societal safety** (UiS MSA 115): Hvordan påvirker fragmentert ansvar og organisering norsk kystberedskap? (How do fragmented responsibility and organization influence Norwegian Coastal disaster and crisis management?).

- **Disaster and Crisis Management** (HiBu KAKRI100), module 1: FN's Sikkerhetsresolusjon 1325. Kvinner, Fred og Sikkerhet. (The UN Security Council Resolution 1325 on women and peace and security).
- **Disaster and Crisis Management** (HiBu KAKRI200), module 2: Hvordan påvirket den norsk-fiansierte opprustningen av Srilankesisk sykepleierutdanning post-tsunami rehabilitering i Batticaloa? (How did the Norwegian financed support of Srilankesisk nurse education influence post-tsunami rehabilitation in Batticaloa?).
- **Staff and Crisis management** (HiBu STAKRI100): På hvilken måte påvirker moderne teknologi kriseledelse? (How is modern technology influencing crisis management?).
- **Philosophy of Science and Research Methods** (UiT STV-3074): Utkast til forskningsdesign for empirisk masteroppgave. (A research design for an empiric master thesis).

In all fields analyzed, from infrastructure and power supply to disaster planning, we conclude that harmonization of international and national regulation is an important risk management tool.

The risk governance theory and societal safety aspects dealt with in the above 7 master program modules have been useful knowledge background when analyzing how regulation of CAM may influence patient safety in Europe.

13.5 Personverneombudet NSD

The project does not include information that should be reported to NSD.

14 References

1. Wiesener S, Falkenberg T, Hegyi G, Hök J, Roberti di Sarsina P, Fønnebø V. Legal Status and Regulation of Complementary and Alternative Medicine in Europe. *Forsch Komplementmed* [Internet]. 2012; 19(Suppl.2):[29-36 pp.]. Available from: <http://www.karger.com/DOI/10.1159/000343125>.
2. Runciman W, Hibbert P, Thomson R, Van Der Schaaf T, Sherman H, Lewalle P. Towards an International Classification for Patient Safety: key concepts and terms. *Int J Qual Health Care* [Internet]. 2009 February 1, 2009; 21(1):[18-26 pp.]. Available from: <http://intqhc.oxfordjournals.org/content/21/1/18.full> DOI:10.1093/intqhc/mzn057.
3. Renn O. Risk governance: coping with uncertainty in a complex world. London: Earthscan; 2008. XX, 455 p.
4. Fintland I, Braut GS. Tilsyn og regulering av risiko i fortid og notid. In: Lindøe PH, Kringen J, Braut GS, editors. Risiko og tilsyn: risikostyring og rettslig regulering. Oslo: Universitetsforlaget; 2012.
5. Baldwin R, Cave M. Understanding Regulation: Theory, Strategy and Practise. Oxford: Oxford University Press; 1999.
6. Weidenhammer W, Lewith G, Falkenberg T, Fønnebø V, Johannessen H, Reiter B, et al. EU FP7 Project 'CAMbrella' to Build European Research Network for Complementary and Alternative Medicine. *Forsch Komplementmed* [Internet]. 2011; 18(2):[69-76 pp.]. Available from: <http://www.karger.com/DOI/10.1159/000327310>.
7. The Roadmap for European CAM Research; An explanation of the CAMbrella project and its key findings. In: Reiter B, editor. www.cambrella.eu/press; CAMbrella; 2012.
8. What is CAM? [Internet] Bethesda, Maryland, USA: National Institutes of Health; National Center for Complementary Medicine (NCCAM); 2008 [updated July 2011; cited 2012]; Available from: <http://nccam.nih.gov/health/whatiscam/#types>.
9. The National Center for Complementary Medicine (NCCAM). What Is Complementary and Alternative Medicine? : NCCAM; 2012 [cited 2012 12 November]; Available from: <http://nccam.nih.gov/health/whatiscam>.
10. Fønnebø V, Riddervold K, Wiesener S. EU proposal full title: "The Patients' Rights in Cross-border Healthcare – Directive 2011/24/EU. Interactions with research when national healthcare legislation and regulation varies". Proposal acronym: CAMCrossEurope: Type of funding scheme: Coordination and Support Action (Supporting) Work programme topics addressed: 4.Other actions across the health theme. Health 2013. 4.1-2. Interactions between EU legislation and health research and/or innovation and the effects of its application and implementation on health research and/or innovation. FP7-Health-2013-Innovation-1. 2012.
11. Wiesener S, Fønnebø V. CAM in Europe - a complex legal and regulative situation. Will harmonized EU-wide regulation strengthen CAM research and practice? Paper

presented at: An international and interdisciplinary conference, Regulation and Professionalization in Complementary and Alternative Medicine: historical perspectives and contemporary concerns; 5 May 2011; Hornton Grange, University of Birmingham, United Kingdom (UK).

12. DIRECTIVE 2011/24/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 9 March 2011, on the application of patients' rights in cross-border healthcare (OJ L 88, 4.4.2011, p.45), (2011).

13. Committee on the Use of Complementary Alternative Medicine by the American Public. Complementary and Alternative Medicine in the United States [monograph online]: The National Academies Press; 2005 [cited 2012 December]. Available from: http://www.nap.edu/openbook.php?record_id=11182&page=R1.

14. Lindøe P, Kringen J, Braut GS. Risiko og tilsyn. Oslo: Universitetsforl.; 2012. 287 p.

15. Boe E. Innføring i juss: juridisk tenkning og rettskildelære. Oslo: Universitetsforl.; 2010. 483 p.

16. Charles Simpson DC CHP Medical Director. Creating a Culture of Patient Safety in Complementary & Alternative Medicine (CAM). [Internet] Portland, Oregon: The CPH group: Complementary healthcare plans e-journal; 2005 [cited 2012 21 October].

17. Committee on Quality of Health Care in America, Institute of Medicine. To Err Is Human: Building a Safer Health System [monograph online]: The National Academies Press; 2000 [cited 2012 December]. Available from: http://www.nap.edu/openbook.php?record_id=9728.

18. Hood C, Rothstein H, Baldwin R. The government of risk: understanding risk regulation regimes. Oxford: Oxford university press; 2010. xiii, 217 p.

19. Molven O, Ferkis J, editors. Healthcare, Welfare and Law: Health legislation as a mirror of the Norwegian welfare state. Oslo: Gyldendal Akademisk; 2011.

20. Molven O. Health personnel - their rights and duties. In: Molven O, Ferkis J, editors. Healthcare, Welfare and Law: Health legislation as a mirror of the Norwegian welfare state. Oslo: Gyldendal Akademisk; 2011. p. 115 - 28.

21. Braut GS. The requirement to practice in accordance with sound professional standards. In: Molven O, Ferkis J, editors. Healthcare, Welfare and Law: Health legislation as a mirror of the Norwegian welfare state. Oslo: Gyldendal Akademisk; 2011. p. 139-49.

22. Treaty of Lisbon amending the Treaty on European Union and the Treaty establishing the European Community, signed at Lisbon, 13 December 2007, entered into force December 1, 2009, (2007).

23. Fønnebø V, Falkenberg T, Hegyi G, Roberti di Sarsina P, Wiesener S. Deliverable 9 - report No. 2 - Herbal and homopathic medicinal products. Brussels: CAMbrella; 2012 [cited 2012 30 November]; Available from:

http://uit.no/ansatte/organisasjon/hjem?p_dimension_id=88112&p_menu=42374&p_lang=2.

24. Wiesener S, Falkenberg T, Hegyi G, Hök J, Roberti di Sarsina P, Fønnebø V. Deliverable 9 - Report No. 3 - CAM Regulations in EU/EFTA/EEA. Brussels: CAMbrella; 2012 [cited 2012 30 November]; Available from: http://uit.no/ansatte/organisasjon/hjem?p_dimension_id=88112&p_menu=42374&p_lang=2.
25. DIRECTIVE 2004/38/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 29 April 2004 on the right of citizens of the Union and their family members to move and reside freely within the territory of the Member States, (2004).
26. REGULATION (EC) No 883/2004 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 29 April 2004 on the coordination of social security systems (Text with relevance for the EEA and for Switzerland), (2004).
27. DIRECTIVE 2005/36/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 7 September 2005 on the recognition of professional qualifications (Text with EEA relevance) (OJ L 255, 30.9.2005, p. 22) Amended up to March 2011, (2005).
28. 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, (2001).
29. 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, (2004).
30. 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), (2004).
31. Costigliola V. Mobility of Medical Doctors as an Attribute of the Cross-Border Healthcare: Challenges, Opportunities and Perspectives. In: Costigliola V, editor. Healthcare Overview: Springer Netherlands; 2012. p. 233-44.
32. The European Commission. Regulated professions database. Brussels: EUROPA; 2011 [cited 2012 February 10,]; Available from: http://ec.europa.eu/internal_market/qualifications/regprof/index.cfm?fuseaction=regProf.index.
33. Fisher P, Ward A. Medicine in Europe: Complementary medicine in Europe. BMJ [Internet]. 1994; 309(6947):[107-11 pp.]. Available from: <http://dx.doi.org/10.1136/bmj.309.6947.107>
34. Fonnebo V, Grimsgaard S, Walach H, Ritenbaugh C, Norheim A, MacPherson H, et al. Researching complementary and alternative treatments - the gatekeepers are not at home. BMC Medical Research Methodology [Internet]. 2007; 7(1):[7 p.]. Available from: <http://www.biomedcentral.com/1471-2288/7/7>.

35. The European Commission. European commission enlargement. Brussels: EUROPA; 2012 [cited 2012 October 16]; Available from: http://ec.europa.eu/enlargement/index_en.htm.
36. Wiesener S, Fønnebø V. Deliverable 9 - Reports No. 1, 2 and 3; CAMbrella project FP7-HEALTH-2009, GA No.241951; Work Package 2; Deliverable 9 - Legal status and regulation of CAM in Europe; S.Wiesener, Falkenberg, T, Hegyi, G., Hök, J., Roberti di Sarsina, P., Fønnebø, V. Brussels: CAMbrella; 2012 [cited 2012 30 November]; Available from: http://uit.no/ansatte/organisasjon/hjem?p_dimension_id=88112&p_menu=42374&p_lan_g=2.
37. Maddalena S. Alternative medicines: on the way towards integration?; A comparative legal analysis in Western countries. Bern: University of Neuchâtel School of Law and Economics, Peter Lang Pub, Inc; 2005. 648 p.
38. Legal Status of Traditional Medicine and Complementary/Alternative Medicine : A Worldwide Review [database on the Internet]. World Health Organization. 2001 [cited 9 March 2010]. Available from: http://whqlibdoc.who.int/hq/2001/WHO_EDM_TRM_2001.2.pdf.
39. Ersdal G, CAM-CANCER consortium. How are European patients safeguarded when using complementary and alternative medicine (CAM)? Jurisdiction, supervision and reimbursement status in the EEA area (EU and EFTA) and Switzerland. Tromsø: NAFKAM, University of Tromsø, 2005 28 October. Report No.: Report CAM 21.11.05-1.doc.
40. WHO. National policy on traditional medicine and regulation of herbal medicines: Report of a WHO global survey [Report online]. Geneva: World Health Organization; 2005 [cited 2012 December]. Available from: <http://apps.who.int/medicinedocs/en/d/Js7916e/>.
41. Schäfer W, Kroneman M, Boerma W, van den Berg M, Westert G, Devillé W, et al. Health Systems in Transition:The Netherlands: Health system review [Report online]. Copenhagen: WHO Regional Office for Europe, on behalf of the European Observatory on Health Systems and Policies; 2010 [cited 2012 December]. Available from: http://www.euro.who.int/_data/assets/pdf_file/0008/85391/E93667.pdf.
42. ECHAMP. Homeopathic and Anthroposophic Medicine: Facts and Figures. Second ed: ECHAMP E.E.I.G: European Coalition on Homeopathic and Anthroposophic Medicinal Products E.E.I.G; 2007.
43. ECHAMP. Homeopathy and anthroposophic medicine in the EU: Facts and Figures 2011. Third ed. Brussels: ECHAMP E.E.I.G: European Coalition on Homeopathic and Anthroposophic Medicinal Products E.E.I.G; 2011.
44. ECCH. The Legal Situation for the Practice of Homeopathy in Europe; Revised Edition 2009 [Report online]: European Council for Classical Homeopathy (ECCH); 2009 [cited 2012 December]. Available from: <http://www.homeopathy-ecch.org/images/stories/pdf/legal%20situation%20for%20homeopathic%20practice%20in%20europe.pdf>.

45. ECCH. The Legal Situation for the Practice of Homeopathy in Europe; An ECCH report; Oct 2010; Revised Edition 2011,. Brussels: European Central Council of Homeopaths 2010.
46. ECH (European Committee for Homeopathy). ECH in European Countries. [Internet] Brussels: ECH; 2011 [cited 2011 September 12]; Available from: <http://www.homeopathyeurope.org/countries>.
47. CAMDOC Alliance ECH ECPM ICMART and IVAA. The regulatory status of Complementary and Alternative Medicine for medical doctors in Europe [Report online]. Brussels 2010 [cited 2010 October 4]. Available from: http://www.ivaa.info/userfiles/file/CAMDOCRegulatoryStatus8_10.pdf.
48. Hegyi G. Questionnaire about the status of CAM therapies:("CAMbrella" Project, EU FP 7): Romania. Budapest 2010.
49. CAMbrella Work Package 1. Questionnaire definition and terminology of CAM and Legal status of CAM. In: CAMbrella WP1, editor. München 2010
50. Nissen N, Schunder-Tatzber S, Weidenhammer W, Johannessen H. What Attitudes and Needs Do Citizens in Europe Have in Relation to Complementary and Alternative Medicine? Forsch Komplementmed [Internet]. 2012 [cited 2013 January]; 19(Suppl. 2):[9-17 pp.]. Available from: <http://www.karger.com/DOI/10.1159/000342710>.
51. Brønnøysundregistret. The Brønnøysund Register Centre (Brønnøysundregistret) Brønnøysund: Brønnøysundregistrene; 2011 [cited 2011 October 31]; Available from: <http://www.brreg.no/english/>.
52. FOR-2003-12-11-1500 Forskrift om frivillig registerordning for utøvere av alternativ behandling; (English translation unauthorized: Regulation on public register for providers of alternative treatment), (2003).
53. Stub T, Alraek T, Salamonsen A. The Red flag! risk assessment among medical homeopaths in Norway: a qualitative study. BMC Complement and Altern Med [Internet]. 2012; 12(1):[150 p.]. Available from: <http://www.biomedcentral.com/1472-6882/12/150>.
54. European Policy Brief; The Roadmap for European CAM Research. Brussels: CAMbrella; 2012 [cited 2012 29 November]; Available from: <http://www.cambrella.eu/home.php?il=195&l=deu>.
55. von Ammon K, Frei-Erb M, Cardini F, Daig U, Dragan S, Hegyi G, et al. Complementary and Alternative Medicine Provision in Europe – First Results Approaching Reality in an Unclear Field of Practices. Forsch Komplementmed [Internet]. 2012 [cited 2013 January]; 19(Suppl. 2):[37-43 pp.]. Available from: <http://www.karger.com/DOI/10.1159/000343129>.
56. Fischer HF, Junne F, Witt C, von Ammon K, Cardini F, Fønnebø V, et al. Key Issues in Clinical and Epidemiological Research in Complementary and Alternative Medicine – a Systematic Literature Review. Forsch Komplementmed [Internet]. 2012 [cited 2013

January]; 19(Suppl. 2):[51-60 pp.]. Available from:
<http://www.karger.com/DOI/10.1159/000343126>.

57. Eardley S, Bishop FL, Prescott P, Cardini F, Brinkhaus B, Santos-Rey K, et al. A Systematic Literature Review of Complementary and Alternative Medicine Prevalence in EU. *Forsch Komplementmed* [Internet]. 2012 [cited 2013 January]; 19(Suppl. 2):[18-28 pp.]. Available from: <http://www.karger.com/DOI/10.1159/000342708>.

15 Attachments:

15.1 Article: Legal Status and Regulation of Complementary and Alternative Medicine in Europe.

Wiesener S, Falkenberg T, Hegyi G, Hök J, Roberti di Sarsina P, Fønnebø V. *Legal Status and Regulation of Complementary and Alternative Medicine in Europe*. *Forsch Komplementmed*. 2012;19(Suppl.2):29-36. Available from: <http://www.karger.com/DOI/10.1159/000343125>.

15.1.1 Confirm SW first author FW_ Ms. No. 201206004, Forschende Komplementärmedizin .pdf

15.1.2 First review Ms. No. 201206004, Forschende Komplementärmedizin .pdf

15.1.3 Received version Ms. No. 201206004, Forschende Komplementärmedizin .pdf

15.1.4 Accepted revised version Ms. No. 201206004, Forschende Komplementärmedizin .pdf

15.1.5 Galley Proof Corrections and Reprint Order.pdf

15.2 Conference paper: CAM in Europe - a complex legal and regulative situation. Will harmonized EU-wide regulation strengthen CAM research and practice?

Wiesener S, Fønnebø V. CAM in Europe - a complex legal and regulative situation. Will harmonized EU-wide regulation strengthen CAM research and practice? In: McHale JV, Gale NK, editors. *An international and interdisciplinary conference, Regulation and Professionalization in Complementary and Alternative Medicine: historical perspectives and contemporary concerns*; 5 May 2011; Hornton Grange, University of Birmingham, United Kingdom (UK).

15.3 The description of each country. Template example – Romania

15.4 Template for country emails and telephone conferences

15.5 Template for interviews and descriptions for each country and treatment

15.6 Questionnaire: About the status of CAM therapies. Example: Romania

15.7 Questionnaire: Definitions and terminology of CAM and legal status of CAM. Example: Portugal

15.8 CAMbrella population-based literature review protocol Version 1.5.

Legal Status and Regulation of Complementary and Alternative Medicine in Europe

Solveig Wiesener^a Torkel Falkenberg^{b,c} Gabriella Hegyi^d Johanna Hök^{b,c}
Paolo Roberti di Sarsina^e Vinjar Fønnebø^a

^a National Research Center in Complementary and Alternative Medicine (NAFKAM), Department of Community Medicine, University of Tromsø, Norway

^b Research Group Integrative Care, Division of Nursing, Department of Neurobiology, Caring Sciences and Society, Karolinska Institutet, Huddinge,

^c IC – The Integrative Care Science Center, Sweden

^d Health Science Faculty, Pécs University, Hungary

^e Expert for Non-Conventional Medicine, High Council of Health, Ministry of Health, Bologna, Italy

Keywords

Alternative medicine · Complementary medicine · Regulation · Government regulation · Legislation · European Union · Europe

Summary

Objective: The study aims to review the legal and regulatory status of complementary and alternative medicine (CAM) in the 27 European Union (EU) member states and 12 associated states, and at the EU/European Economic Association (EEA) level. **Methods:** Contact was established with national Ministries of Health, Law or Education, members of national and European CAM associations, and CAMbrella partners. A literature search was performed in governmental and scientific/non-scientific websites as well as the EUROPA and EUR-lex websites/databases to identify documents describing national CAM regulation and official EU law documents. **Results:** The 39 nations have all structured legislation and regulation differently: 17 have a general CAM legislation, 11 of these have a specific CAM law, and 6 have sections on CAM included in their general healthcare 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 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.

Introduction

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 European Union (EU) has, however, repeatedly confirmed that it is up to each member state to organize and regulate their healthcare 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] and other directives indirectly encourage some degree of harmonization. CAM professions can be registered in the European Commission (EC) 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 the EU/European Economic Association (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 EU 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 websites/databases to identify official law documents. The scientific and non-scientific literature was 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 4 countries. Health authorities (if possible both legal and regulatory) were asked to verify the situation described for their specific country. 12 common treatment modalities have been described in detail in each country. In addition, a search was performed in the EUROPA and EUR-lex websites/databases to identify official EU law documents. We searched specifically for information about EU directives regarding European-wide healthcare-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 EU offices and non-government organization (NGO) bodies in Brussels to establish firsthand updated information. Meetings were held with:

- 1 The counsellor for health and food safety at the Mission of Norway to the EU. At the Mission of Norway to the EU we received updated information mainly on the European Free Trade Association (EFTA)/EEA legal connection to EU legislation and the new Patients' Rights in Cross-Border Healthcare Directive 2011/24/EU [3].
- 2 The European Commission Central Library.
- 3 Meetings with the following NGOs provided important additional CAM documents and legal system information as well as viewpoints with regard to EU regulation:
 - International Federation of Anthroposophic Medical Associations (IVAA)
 - International Council of Medical Acupuncture and Related Techniques (ICMART) – EU Liaison Office
 - The Association of the European Self-Medication Industry (AESGP).

We 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 that we have found across all 39 nations is the amazing ability they have demonstrated for structuring legislation and regulation differently in every single country, no matter how small the size of the population.

Of the 39 countries, 17 have a general CAM legislation, 11 of these 17 have a specific CAM law and 6 countries have sections on CAM included in their health laws (like 'law on healthcare' or 'law on health professionals'). In addition to the general CAM legislation, some countries have regulations on specific CAM treatments (fig. 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 healthcare system. We found few similarities in the regulations of the specific CAM treatments between the countries, and it is challenging to find out who is allowed to practice the different treatments.

The 12 common treatment modalities vary considerably with regard to how many countries regulate the profession or practice in some way or another. Acupuncture is regulated in

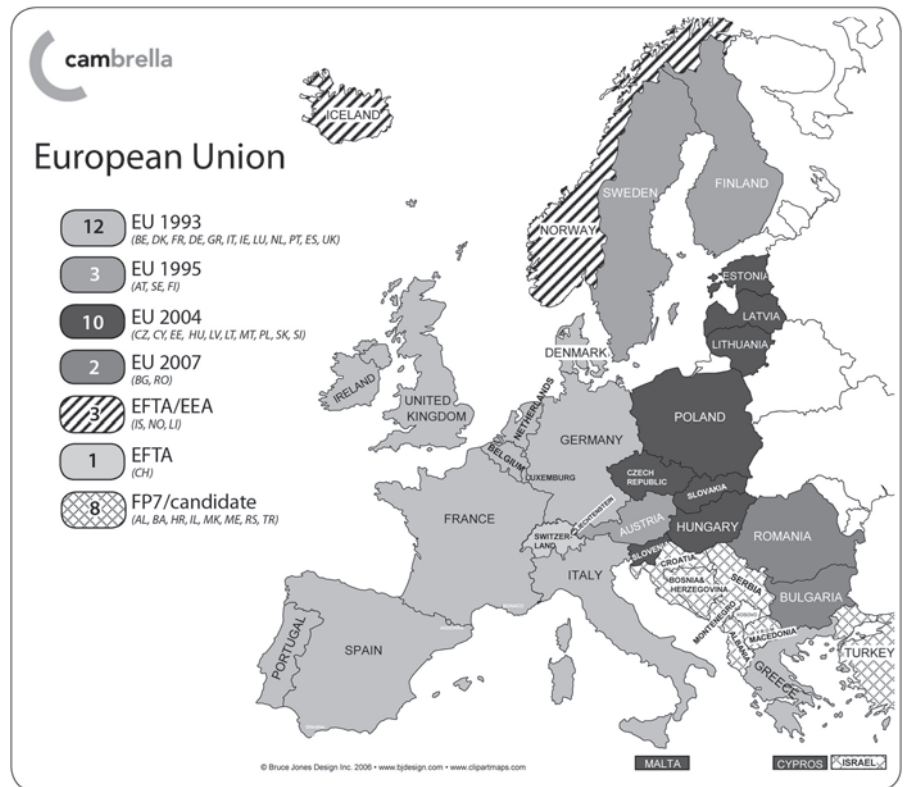


Fig. 1 The relationship of 39 countries to the EU.

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 ‘naturopath/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 ‘natural health practitioner 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.

Figure 4 ‘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 practice homeopathy. If only medical doctors with additional CAM education are allowed to practice, we have put ‘No’ in the column for medical doctors. The same applies for other health personnel. If the regulation (or ab-

sence of regulation) was too unclear for us to be certain, we have inserted a question mark. Since the countries with CAM practitioners like ‘Heilpraktiker’, ‘healer’ and likewise may not be correctly represented, we 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 states within the EU/EEA area are therefore no longer free to uphold a national regulation of medicinal products in violation of the following 3 EU directives.

- 1 Directive 2001/83/EC of the European Parliament and of the Council, of November 6, 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 March 31, 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 March 31, 2004 amending directive 2001/83/EC on the community code relating to medicinal products for human use (Text with EEA relevance) [6].

Until April 30, 2011, herbal medicinal products that were marketed without authorization before this legislation came into force could continue to be marketed under transitional measures defined in directive 2004/24/EC [5]. Now that this

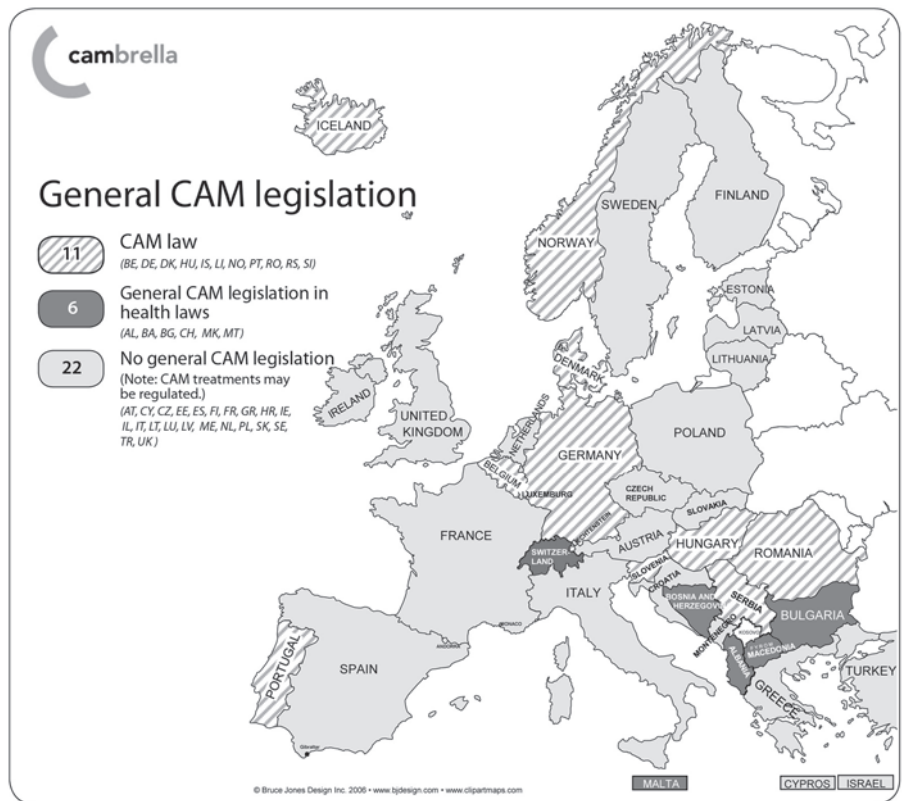


Fig. 2. The status with regard to CAM general legislation in 39 European countries.

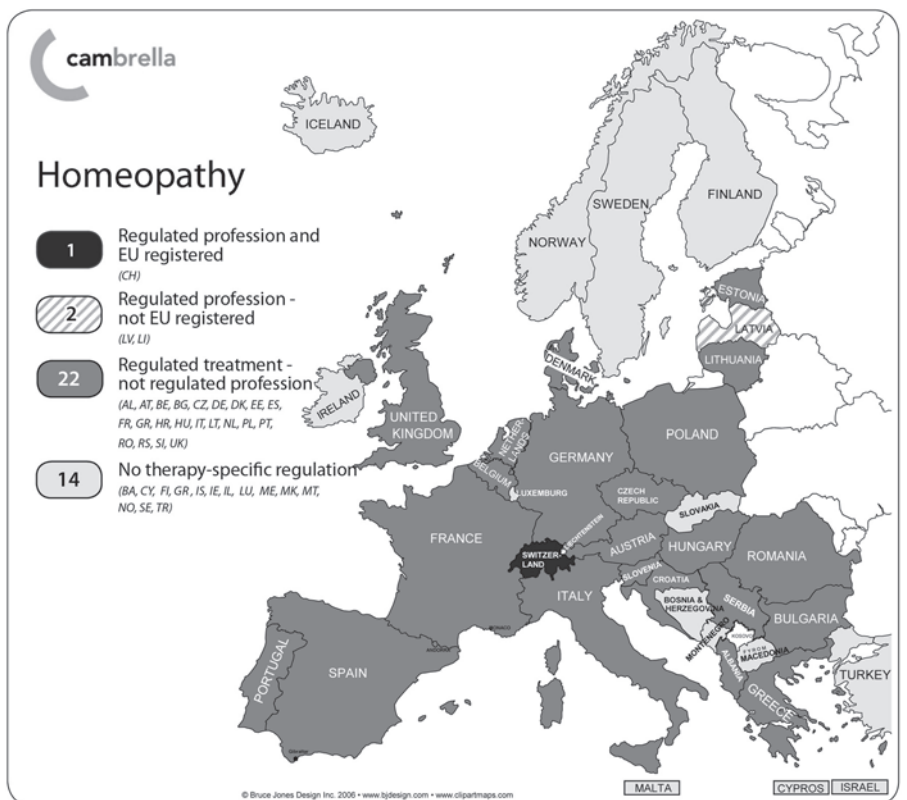


Fig. 3. Homeopathy regulation in 39 European countries.

time limit has expired, all herbal medicinal products that were previously unauthorized must have market authorization according to directives 2001/83/EC, 2004/24/EC, and 2004/27/EC [4–6] 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

Homeopathy - Who may practice

Country	Specific homeopathy treatment regulation	Medical Doctors (MDs)	Medical Doctors with CAM training	Conventional practitioners (CPs) PS3 ¹	Conventional health personell with CAM training	CAM practitioners ²	Other may practice	Other CAM legislation	Notes
Albania	Yes	?	?	?	?	?	?	Yes	
Austria	Yes	Yes	Yes	?	?	?	No	Yes	
Belgium	Yes	Yes	Yes	Yes	Yes	?	No	Yes	
Bosnia and Herz.	No	Yes	Yes	?	?	?	No	No	
Bulgaria	Yes	Yes	Yes	No	No	No	No	Yes	
Croatia	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	
Cyprus	No	Yes	Yes	No	No	No	No	Yes	
Czech Republic	Yes	No	Yes	No	No	No	No	Yes	
Denmark	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	
Estonia	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	
Finland	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	
France	Yes	Yes	Yes	Yes	Yes	No	No	Yes	
Germany	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Heilpraktiker
Greece	Yes	Yes	Yes	Yes	Yes	Yes	?	Yes	
Hungary	Yes	No	Yes	No	No	No	No	Yes	
Iceland	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Healer
Ireland	No	Yes	Yes	Yes	Yes	Yes	Yes	No	
Israel	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	
Italy	Yes	Yes	Yes	No	No	No	No	Yes	
Latvia	Yes	Yes	Yes	No	No	No	No	Yes	
Liechtenstein	Yes	Yes	Yes	Yes	Yes	No	No	Yes	
Lithuania	Yes	No	Yes	No	No	No	No	Yes	
Luxembourg	No	Yes	Yes	?	?	No	No	Yes	
Macedonia	No	Yes	Yes	?	?	?	?	Yes	
Malta	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	
Montenegro	No	Yes	Yes	?	?	?	?	No	
Netherlands	No	Yes	Yes	Yes	Yes	Yes	?	Yes	
Norway	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	
Poland	Yes	Yes	Yes	Yes	Yes	Yes	?	Yes	
Portugal	Yes	Yes	Yes	Yes	Yes	Yes	?	Yes	
Romania	Yes	No	Yes	No	No	No	No	Yes	
Serbia	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	
Slovakia	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	
Slovenia	Yes	Yes	Yes	?	?	?	No	Yes	
Spain	Yes	Yes	Yes	?	?	?	No	Yes	
Sweden	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	
Switzerland	Yes *	Yes	Yes	?	?	?	?	Yes	*Naturopath/homeopath
Turkey	No	Yes	Yes	?	?	?	?	Yes	
United Kingdom	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	

1) Conventional practitioners (CPs) (PS3 post-secondary level 3-4 years)

2) CAM practitioner (CAM trained personnel, medical trained, DSE diploma post- secondary education level)

Fig. 4. An overview of groups that can legally practice homeopathy in 39 European countries.

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 4 administrative procedures that can be followed to obtain a market authorization for these products (standard, well-established use, and 2 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 December 31, 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 2 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 EU and the Council of Europe that may influence the professional practice of CAM, whether practiced by an authorized/licensed healthcare provider or by a provider without such authorization/licensing, will also affect the conditions under which patients can receive CAM treatment(s) in Europe.

We have found no direct EU legislation of CAM except for directives concerning CAM medicinal products described above. 2 resolutions deal with non-conventional medicine:

- Resolution A4-0075/97: ‘Resolution on the status of non-conventional medicine’. This is part of the European Parliament resolution on how non-conventional medicine should be included more formally as a special field in the European legislation [1].
- Resolution 1206 (1999): ‘A European approach to non-conventional medicines’ of the Parliamentary Assembly of the Council of Europe resolution on non-conventional medicine [2].

How legislation connected to ‘The 4 Freedoms’ is handled in EU/EEA, influences the national CAM legislation and legislation that impacts directly or indirectly on CAM of the individual states. 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 practice CAM according to national health regulation. The EU-regulated professionals database includes only a few CAM professions in some member states. We have 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 that 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 healthcare 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 in 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 healthcare delivery to European citizens. When CAM professions in some countries are tightly regulated, while the same professional categories in other countries are totally unregulated, establishing a common collegial ground is very challenging.

When *researchers* cross borders they will find 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 medical 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 healthcare. Developing the European legislation of CAM by simply adapting the criteria of conventional medicine will probably be inadequate for regulation of the CAM field. Similar to the 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.

In particular, the Patients' Rights in Cross-Border Healthcare Directive [3] 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 healthcare 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], which clearly state that the individual member states have 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 countries to voluntarily harmonize their legislation and regulation of CAM with other European states. If this had been done to a greater degree, both patients and providers would be able to benefit from The Right to Move and

Reside Freely Directive [15], the Professional Qualifications Directive [11], the Patients' Rights in Cross-Border Healthcare Directive [3], the Services Directive [16], and the Social Security Regulation [17].

There are in principle, therefore, 2 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 has repeatedly 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 under-regulation 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 EU and the European countries. This could be a potential template for development of harmonized regulation of CAM professions in Europe [18].

Acknowledgements

We thank the following for valuable contributions to the text: S. Connolly, S. Gordon, F. de Herdt, R. Kempenich, T. Nicolai, T. Kristiansen Tunby, and P. Zimmermann. We also thank the following for technical assistance: K. Riddervold and Å. Sohlén.

Disclosure Statement

This project was funded as part of CAMbrella Work Package 2 FP7-HEALTH-2009-3.1-3 (Grant No. 241951).

References

- 1 The European Parliament. Resolution on the status of non-conventional medicine. Brussels, The European Union (OJ C 182, 16/06/1997 P. 0067), 1997.
- 2 Council of Europe: Resolution 1206 (1999). An European approach to non-conventional medicines; November 4, 1999; in Official Gazette of the Council of Europe. Resolution. Strasbourg, Council of Europe, 1999.
- 3 Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011, on the application of patients' rights in cross-border healthcare (OJ L 88, 4.4.2011, p.45), 2011.
- 4 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, 2001.
- 5 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, 2004.
- 6 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), 2004.
- 7 Ersdal G, CAM-CANCER consortium: How are European patients safeguarded when using complementary and alternative medicine (CAM)? Jurisdiction, supervision and reimbursement status in the EEA area (EU and EFTA) and Switzerland. Tromsø, NAFKAM, University of Tromsø, 2005. 28 October, Report No.: Report CAM 21.11.05-1.doc.
- 8 Legal Status of Traditional Medicine and Complementary/Alternative Medicine: A Worldwide Review [database on the Internet]. World Health Organization, 2001. http://whqlibdoc.who.int/hq/2001/WHO_EDM_TRM_2001.2.pdf. (09.03.2010).

- 9 Maddalena S: *Alternative Medicines: On the Way towards Integration? A Comparative Legal Analysis in Western Countries*. Bern, Peter Lang, 2005, p. 648.
- 10 Council Regulation (EEC) No 2309/93 of 22 July 1993 laying down community procedures for the authorization and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products (OJ No L 214 of 24. 8. 1993, p. 1), 1993.
- 11 Directive 2005/36/EC of the European Parliament and of the Council of 7 September 2005 on the recognition of professional qualifications (text with EEA relevance), 2005.
- 12 NHS core principles: www.nhs.uk/NHSEngland/thenhs/about/Pages/nhscoreprinciples.aspx. (07.06.2012).
- 13 Fønnebo V, Grimsgaard S, Walach H, Ritenbaugh C, Norheim AJ, MacPherson H, Lewith G, Launsø L, Koithan M, Falkenberg T, Boon H, Aickin M: Researching complementary and alternative treatments – the gatekeepers are not at home. *BMC Med Res Methodol* 2007;7:7.
- 14 Treaty of Lisbon amending the Treaty on European Union and the Treaty establishing the European Community, signed at Lisbon, December 13, 2007, entered into force December 1, 2009.
- 15 Directive 2004/38/EC of the European Parliament and of the Council of April 29, 2004 on the right of citizens of the union and their family members to move and reside freely within the territory of the member states, 2004.
- 16 Directive 2006/123/EC of the European Parliament and of the Council of December 12, 2006 on services in the internal market, 2006.
- 17 Regulation (EC) No. 883/2004 of the European Parliament and of the Council of April 29, 2004 on the coordination of social security systems (text with relevance for the EEA and for Switzerland), 2004.
- 18 The Norwegian Physiotherapist Association: Personal communication, the leader of the central board, Oslo, 2012.

From: [Fønnebø Vinjar Magne](mailto:Fonnebo.Vinjar.Magne)
To: [Wiesener Solveig](mailto:Wiesener.Solveig)
Subject: FW: Ms. No. 201206004, Forschende Komplementärmedizin
Date: 20. juni 2012 15:26:08

Kjære Solveig,

Da var det i boks!!

Vinjar

-----Original Message-----

From: Piepiorka, Anna [<mailto:a.piepiorka@karger.de>]
Sent: 20. juni 2012 14:52
To: Fønnebø Vinjar Magne
Subject: AW: Ms. No. 201206004, Forschende Komplementärmedizin

Dear Vinjar,

No problem: I have just changed it in the system and will also change it in the manuscript as soon as the review is through.

Sincerely yours,

Anna

Anna Piepiorka
Editorial Office
t +49 761 45207-26
a.piepiorka@karger.de

S. Karger Verlag für Medizin und Naturwissenschaften GmbH | Wilhelmstrasse 20A | 79098 Freiburg
| Deutschland t +49 761 452070 | f +49 761 4520714 | www.karger.com

Registergericht Freiburg HRB 4256
Geschäftsführer Dr. Thomas Karger | Gabriella Karger Travella | Sibylle Gross

-----Ursprüngliche Nachricht-----

Von: Fønnebø Vinjar Magne [<mailto:vinjar.fonnebo@uit.no>]
Gesendet: Mittwoch, 20. Juni 2012 13:05
An: Piepiorka, Anna
Cc: Wiesener Solveig
Betreff: RE: Ms. No. 201206004, Forschende Komplementärmedizin

Dear Anna,

We have made a change in the order of the authors.

I will be the last author, and Solveig Wiesener (who is currently listed as the last author) will be the first author. She will also take the role as corresponding author.

She has the following contact information:

Solveig Wiesener, National Research Center in Complementary and Alternative Medicine (NAFKAM),
Institute of Community Medicine, University of Tromsø, Norway
Phone: +47 77646650
Fax: +47 77646866
e-Mail: Solveig.Wiesener@uit.no

Vinjar

-----Original Message-----

From: a.piepiorka@karger.de [<mailto:a.piepiorka@karger.de>]

Sent: 13. juni 2012 08:29

To: Fønnebø Vinjar Magne

Subject: Ms. No. 201206004, Forschende Komplementärmedizin

Forschende Komplementärmedizin/Research in Complementary Medicine
MS: 201206004 Legal status and regulation of CAM in Europe

Dear Dr. Fønnebø,

Thank you very much for submitting your manuscript entitled "Legal status and regulation of CAM in Europe" to be published in the supplement "Cambrella" in Research in Complementary Medicine. It will now be forwarded to Harald Walach in order to have it reviewed.

In the meantime, please make sure to hand in the copyright transfer statement which you can find at

http://oper1.karger.com/xpresstrack/submissions/copyright_transfer_statement_fkm.pdf.

It is important that all authors sign the form.

When enquiring about your manuscript, please always quote the reference number 201206004.

For information regarding the status of your manuscript and for future submissions to Research in Complementary Medicine you can access this system by logging into the journal's online peer review system as follows:

<http://www.karger.com/fok>

Then click on "Online submission" and then on "Manuscript Check", each at the right-hand bar, and enter:

Logon Name: vinjar.fonnebo@uit.no

Password: sacslv66

Yours sincerely,

Anna

Anna Piepiorka
Editorial Office
t +49 761 45207-26
a.piepiorka@karger.de

S. Karger Verlag für Medizin und Naturwissenschaften GmbH | Wilhelmstrasse 20A | 79098 Freiburg
| Deutschland t +49 761 452070 | f +49 761 4520714 | www.karger.com

Registergericht Freiburg HRB 4256
Geschäftsführer Dr. Thomas Karger | Gabriella Karger Travella | Sibylle Gross

From: a.piepiorka@karger.de
To: [Wiesener Solveig](#)
Subject: Ms. No. 201206004, Forschende Komplementärmedizin
Date: 31. juli 2012 09:04:43

Ms No.: 201206004
Title: Legal status and regulation of CAM in Europe

Dear Solveig,

Thank you very much for submitting your above mentioned manuscript to the special issue "Cambrella" of our journal Forschende Komplementärmedizin/Research in Complementary Medicine. It has now been evaluated by Harald Walach and we are pleased to inform you that your paper has been found suitable for publication, providing you can make the changes and amendments suggested by the reviewer.

Below are remarks Harald Walach have asked us to share with you:

This is a nice manuscript, which in principle can be taken as it is. I have, however, two minor typo-corrections, which I would ask to correct before submitting the final manuscript.
Also, it might be useful if you flesh out your example about how the physiotherapists achieved harmonisation with a few sentences so that readers can understand how such a harmonisation process might actually work. Normally, the journal charges for colour reproductions. Please be in contact with the editorial office regarding this issue.

Minor corrections:

p 9: ?We found few find similarities ?? needs correcting
p 9: naprapathy please provide short explanation (perhaps ?some form of manipulative therapy? or something similar)
p 15: CAM practise should be ?practice? (as it is the noun, not the verb)

While checking the manuscript for consistency with formal requirements, I found the following:

- Authors are required to disclose any sponsorship or funding arrangements relating to their research and all authors should disclose any possible conflicts of interest. Please provide a Disclosure Statement at the end of the text of the article.

Please send your reply and the revised version to the Editorial Office online by logging into the submission website with your personal login name and password:

URL: <http://www.karger.com/fok>

Then click on "Online submission" and "Manuscript Check" both at the right-hand bar.

Login name: Solveig.Wiesener@uit.no

Password: 2825

In case of any questions I am glad to help!

Yours sincerely,
Anna

Anna Piepiorka
Editorial Office
t +49 761 45207-26
a.piepiorka@karger.de

From: a.piepiorka@karger.de
To: [Wiesener Solveig](#)
Subject: Ms. No. 201206004, Forschende Komplementärmedizin
Date: 24. august 2012 12:47:35

Ms. No. 201206004

Dear Solveig,

Thank you for submitting a revised version of your manuscript entitled "Legal status and regulation of CAM in Europe" to "Research in Complementary Medicine". I especially thank you very much for your effort to revise the figures and turn them monochrome.

The paper will now be forwarded to Harald Walach for a last review and we shall inform you as soon as possible about his decision.

For information regarding the status your manuscript and for future submissions to "Research in Complementary Medicine", please logon to the manuscript tracking system with your personal logon name and password as follows:

<http://www.karger.com/fok>

Then click on "Online Submission" and then on "Manucript Check" (each on the right-hand bar) to enter

Logon Name: Solveig.Wiesener@uit.no
Password: 2825

All the best,
Anna

Anna Piepiorka
Editorial Office
t +49 761 45207-26
a.piepiorka@karger.de

S. Karger Verlag für Medizin und Naturwissenschaften GmbH | Wilhelmstrasse 20A | 79098 Freiburg
| Deutschland t +49 761 452070 | f +49 761 4520714 | www.karger.com

Registergericht Freiburg HRB 4256
Geschäftsführer Dr. Thomas Karger | Gabriella Karger Travella | Sibylle Gross

From: a.piepiorka@karger.de
To: [Wiesener Solveig](#)
Subject: Ms. No. 201206004, Forschende Komplementärmedizin
Date: 4. september 2012 08:18:09

Ms No.: 201206004
Title: Legal status and regulation of CAM in Europe

Dear Solveig,

Thank you for submitting a revised version of your manuscript to the CAM-issue of "Forschende Komplementärmedizin/Research in Complementary Medicine". We are pleased to inform you that it has now been accepted by Harald Walach in its present form.

As soon as your article has been proofread, I will send you a proof for corrections and approval.

In case of any questions please do not hesitate to contact me.

All the best,

Anna

Anna Piepiorka
Editorial Office Forschende Komplementärmedizin

S. Karger Verlag für Medizin und Naturwissenschaften GmbH
Wilhelmstraße 20A
79098 Freiburg
Germany
Tel: +49 761 45 20726
Fax: +49 761 45 20714
Mail: a.piepiorka@karger.de
<http://www.karger.com/fok>
Registergericht Freiburg *** HRB 4256
Geschäftsführer: Dr. Thomas Karger, Gabriella Karger Travella, Sibylle Gross

Confidential Note:

This e-mail may contain confidential and/or privileged information. If you are not the intended recipient (or have received this e-mail in error) please notify the sender immediately and destroy this e-mail. Any unauthorised copying, disclosure or distribution of the material in this e-mail is strictly forbidden.

From: [Zoller, Sebastian](#)
To: [Wiesener Solveig](#)
Subject: Galley Proof Corrections and Reprint Order
Date: 10. oktober 2012 10:19:33
Attachments: [Reprint_order_2012.pdf](#)
[FKM_201206004_Wiesener_lekt_sr.pdf](#)
[06004_wiesener.pdf](#)

Dear Ms. Wiesner,

Your work will go to press shortly. Please observe the following instructions carefully in order to expedite the final stages of production.

Galley Proofs (PDF)

Attached you find the galley proof (PDF file) together with your edited manuscript. Please correct the galley proof printouts and return them to us by fax, **within 5 days** of receipt. For proof-reading, you are the most important person. Please check the text and reproductions for misprints as well as for correct layout. Errors you miss may not be caught by someone else. You, the author, are responsible for the accuracy of the contents.

Corrections must be clear and legible. Make corrections but avoid changes. Changes to the text are expensive and can delay publication. If the cost of changes (other than corrections of typesetting errors) in the text and illustrations exceeds 10% of the cost of typesetting and filmmaking, you will be billed accordingly.

Please respect our deadline. If we have not received your corrected proofs by the deadline date, we will assume that your contribution is ready for printing.

Please note that the galleys are not representative for exact positioning and printing quality.

Questions of the Editor

See the questions and comments in the edited manuscript.

Reprints

Reprints are available at prices determined by article length and quantity (see price list). Please send us your order using the order form attached to this mail, together with your galley proofs. Reprint orders at a later date are subject to considerably higher prices.

Reprint orders are processed soon after publication of the book or journal. Reprints ordered from outside Germany are sent via surface mail after receipt of payment. Airmail delivery is available on request, and at an extra charge.

Thank you for your cooperation.

Yours sincerely,

Sebastian Zoller
Druck- u. Medientechniker | Herstellung
s.zoller@karger.de

Regulation and Professionalization in Complementary and Alternative Medicine: historical perspectives and contemporary concerns

An international and interdisciplinary conference

5 May 2011, 9am-5pm

Hornton Grange, University of Birmingham, UK



wellcometrust

Regulation and Professionalization in Complementary and Alternative Medicine: historical perspectives and contemporary concerns

An international and interdisciplinary conference

The provision and use of traditional, complementary and alternative medicines (usually referred to as CAM) has been growing in the UK and other industrialized nations over the last 40 years. CAMs include traditional healing practices, such as acupuncture and Ayurveda, complementary treatments such as aromatherapy or massage, and alternative medical systems, such as osteopathy or homeopathy.

To date, most of the academic research in CAM has focused on issues of efficacy and effectiveness, rather than on historical, social and legal aspects of practice. This interdisciplinary conference will focus on two central concepts: **regulation**, the legal frameworks for practitioners (products will not be covered) and **professionalization**, the socio-political process of becoming a recognised profession. Both concepts will be considered within their **historical context** and in terms of their conceptual purchase in terms of **contemporary concerns and debates**.

Conference Organisers

Dr Nicola Gale (n.gale@bham.ac.uk)

Prof Jean McHale (j.v.mchale@bham.ac.uk)

Prof Heather Draper (h.draper@bham.ac.uk)

Dr Jonathan Reinartz (j.reinartz@bham.ac.uk)

Ms Beatrice Gehr-Swain (b.n.gehrswain@bham.ac.uk)

This conference is supported financially by **The Wellcome Trust** and hosted by **The Centre for Health Law, Science and Policy**, **The History of Medicine Unit**, **The Centre for Biomedical Ethics** and **The Complementary and Alternative Medicine Birmingham Research Alliance (CAMBRA)** at The University of Birmingham.

For further details, please see www.cam.bham.ac.uk



wellcometrust

Conference Programme

- 9.00am Registration (tea and coffee)
- 9.30am Welcome (Jean McHale and Nicola Gale)
- 9.45am KEYNOTE
Mike Saks, Professor of Health and Community Studies and Provost at University Campus Suffolk, UK
Power and professionalization in CAM: historical and contemporary perspectives
- 10.30am Break (tea and coffee)
- 10.45am WORKSHOP: professionalization (Chair: Nicola Gale)
(see below for details of workshop format)
- Sandy Welsh, Heather Boon, Merrijoy J Kelner, Beverly Wellman (Canada) – *Traditional Chinese Medicine and Acupuncture Practitioners and the Canadian Health Care System: The Role of the State in Creating the Necessary Vacancies.*
 - Jane Wilkinson, Nicola Gale (UK) – *Towards a learning profession: A critical evaluation of the relevance of clinical governance for complementary and alternative healthcare services*
 - Jane Adams (UK) – *Developing Naturopathy in Britain 1920-1950*
 - Sarah Cant (UK) – *'The Knowledgeable Doer': Nurse and midwife integration of complementary and alternative medicine in NHS hospitals.*
- 12.20 pm Group photograph
- 12.30 pm Lunch and Postgraduate Poster Presentations
- Joana Almeida (UK) - *Recent CAM Manoeuvring within the Mainstream Health-Care System in Portugal*
 - Romila Santosh (UK) - *The current practice of Ayurveda in the UK. Practitioner and patient perspectives.*

1.15 pm KEYNOTE

Julie Stone, Visiting Professor in Ethics, Peninsula Medical School, UK
Aspiration, Integration, Regulation: CAM's uneasy relationship with the State

2.00 pm WORKSHOP: regulation (Chair: Jean McHale)

(see below for details of workshop format)

- Marie-Andrée Jacob (UK) – *'A responsible body of scientific opinion': Research integrity and conduct, and the regulation of CAM*
- Ayo Wahlberg (Denmark) – *What is a 'dangerous' practitioner? Technologies of assurance in CAM practice today*
- Ruth Barcan (Australia) – *Intuitive Medicine: Ethics, Regulation and Incommensurability*
- Solveig Wiesener, Vinjar Fønnebø (Norway) – *CAM in Europe – a complex legal and regulative situation. Will harmonized EU-wide regulation strengthen CAM research and practice?*

3.45 pm Break (tea and coffee)

4.15 pm Panel Discussion and Moving Forward

Panel Members: Prof Julie Stone, Prof Marie Fox, Prof Heather Draper, Dr Jonathan Reinartz

The purpose of the conference is to look at the past, present and future of CAM regulation and professionalization, and to develop a framework for future research in the field. This final session will draw together key themes that have emerged, discuss publications and a potential future research programme.

- ⑩ *Is enhanced professionalization/ regulation inevitable and/or desirable?*
- ⑩ *Is CAM really any different than any other area of medicine in relation to the professionalization/ regulation issues that it raises and, if so, in what ways?*
- ⑩ *Are professionalization and regulation inextricably linked?*
- ⑩ *What is the impact of the discourse of patients' rights upon professionalization and regulation in CAM?*
- ⑩ *Will the EU provide a fundamental driver to change in this area in the future?*
- ⑩ *Are we learning from history or are we 'reinventing the wheel'?*
- ⑩ *What is going to drive the debate forward in the next few years?*

5.00pm Close

CAM in Europe – a complex legal and regulative situation. Will harmonized EU-wide regulation strengthen CAM research and practice?

Wiesener S., Fønnebø V.

Conventional medicine in Western countries is generally organized similarly across countries, continents and cultures. Each country regulates the practice of medicine along mutually recognizable patterns. The professional categories are similar, and within EU/EEA (the European Economic Area) an established system of mutual recognition of the other countries' licensing or authorization is in place. This system is in place despite the Lisbon Treaty declaration of the right of each country to organize the health care system separately from each other. EU has deliberately decided not to introduce an EU-wide regulation of health care. The substantial similarity of the national health care systems, however, enables strong international collaborations within both research and practice.

Complementary and Alternative Medicine (CAM) is a diverse system of "health care" which has only one common feature across Europe: It is alternative or complementary to conventional health care. Although this system of care is present throughout Europe and beyond, it does not necessarily have the same name, structure or function within each country. There is no implicit commonality shared by either the national authorities or the practitioner communities.

The Pan-European research network CAMbrella was established in 2010 funded by the 7th Framework Programme in EU. The objective of this coordination project is to assess CAM across Europe, and come up with a roadmap for future research to ensure the peoples of Europe safe and effective practices also in this area of "health care". One of the main aims of this project is to review the legal and regulatory status of CAM, and indicate how legal and regulatory differences can be taken into account both in research initiatives and efforts to secure equal access to health services across Europe.

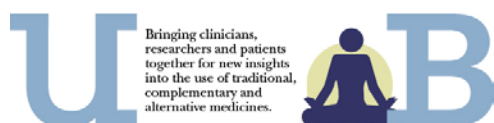
Material and Methods

Thirty-nine countries covering EU, EFTA, EU candidate -and associated countries are included in this overview. In order to describe the legal and regulatory status we have collected legal and regulation documents from each country and EU. Additional information has also been acquired by questionnaires and personal visits.

CAM practitioners are heterogeneously classified and the CAM terminology differs within Europe. A full description of CAM terminology is forthcoming under the responsibility of a different group within CAMbrella.

To identify how CAM providers and treatments are legislated and regulated it was necessary to study both general health care legislation/regulation and, if established, CAM legislation/regulation. This is due to the fact that CAM can either be legislated/regulated in general health care legislation/regulation as something that is or is not included there, or it can be separately legislated/regulated. It was also necessary to relate to differences in education, curriculums, and licensing/authorization/registry systems.

PLEASE NOTE: These discussion papers have been prepared for this conference and should not be circulated to non-delegates. In addition they should not be cited without written permission from the authors.



Supported by
wellcometrust

The work in the CAMbrella project is still under way, and we can therefore at this moment in time only report on EU-wide systems that potentially affect the legislation/regulation of CAM within countries and some aspects of legislation/regulation within individual countries.

Results

Europe -policies and legislation

Health policies are a national responsibility for the EU Member States. This is confirmed in the Lisbon Treaty in TITLE XIV Public Article 168 number 7:

"Union action shall respect the responsibilities of the Member States for the definition of their health policy and for the organisation 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."

The Parliamentary Assembly of the Council of Europe passed a Resolution already in 1999 supporting the EU view, but at the same time calling for a common European approach to what they classify as "non-conventional medicine": *"In the health field, it is important to preserve the diversity of national legislation and practise that is one of Europe's assets: people's attachment to their own systems and tradition must not be called into question. Nevertheless, the Assembly believes that a common European approach to non-conventional medicine based on the principle of patients' freedom of choice in health care should not be ruled out."....."The Assembly believes that the best guarantee for patients lies in a properly trained profession, which is aware of its limitations, has a system of ethics and self-regulation and is also subject to outside control."* [1]

EU has established several legal documents that influence national health and CAM related legislation in the EU and EU-associated countries. The new Cross-border Health Directive (The Patient Rights Directive) passed in February 2011[2] is one example of how EU legislation will influence national health reimbursement systems, health priorities and patient safety aspects. According to this Directive a person living in the EEA-area can choose health treatment in all the EEA Member States. Expenses will be reimbursed according to the home country regulations while treatment/provider regulations will follow the legislation in the country where the treatment has been given. Since the reimbursement and regulation of CAM practices differ substantially between countries, the consequences of this Directive could be that patients' rights with regard to equal access to health treatment in Europe could be challenged.

"The Four Freedoms" stated in the EU Treaties aim to enable goods, services, capital and persons to move freely within EEA. Education, training, employment, enterprise and civil protection are fields included in the regulations. National regulations of CAM practitioners, treatments, supervision and reimbursement do not follow an EU-wide harmonized system and are not covered by mutual recognition systems. Consequently the differences in CAM regulation challenge the free movement of patients and practitioners in Europe.

As mentioned in the introduction EU has required all countries to mutually recognize certain professional categories, some of these categories include doctors, nurses and other health care personnel. This mutual recognition requires established systems of licensing/authorization in each country. A similar mutual recognition for CAM practitioners has not been established.

Individual countries -policies and legislation

PLEASE NOTE: These discussion papers have been prepared for this conference and should not be circulated to non-delegates. In addition they should not be cited without written permission from the authors.



Supported by
wellcometrust

Even though some countries studied have passed specific CAM legislation/regulation over the past few years, there are few, if any, signs of harmonization in Europe. Regional legislation/regulation similarities seem more based on common historical development within health treatment cultures than a conscious effort to facilitate cross-border cooperation and ease of access for patients.

We have, however, identified two main approaches to regulation; countries where all practice of CAM is regulated in some way or another (Examples: Germany, Hungary, Belgium) and countries that do not regulate the field at all or only regulate some of the CAM treatments (Examples: Latvia, Norway, Sweden)[3].

Countries regulating CAM often do it within the framework of health care regulation in general. Some countries limit the licence to practice CAM to medical doctors (Example: France), while other countries have started to licence also other practitioner categories (Example: Hungary).

Reimbursement of CAM treatment also varies considerably within Europe. Most countries reimburse no expenses associated with CAM treatments, but there are examples of exceptions to this: Some health insurance companies in Germany reimburse selected treatments, Switzerland has decided (after a referendum) to reimburse five main modalities from 2012 and Norway covers CAM treatments given in hospitals.

Risk and safety aspects

The differences in legislation make it challenging to ensure safe practice of CAM across boundaries in the EU/EEA area. All countries have established national health supervision systems for health professionals (doctors, nurses, midwives a.o.). This system will only apply to CAM practitioners in countries where the same practitioners are regulated as health personnel. In countries where "only doctors are allowed to treat ..." sick individuals one should think that patient safety is ensured. But even there the safety of patients with regard to CAM treatments could be at risk. With the EU mutual recognition of medical doctors, some physicians could be well qualified for CAM treatments, while others, immigrating from countries with no education/training in CAM in the medical curriculum, will be totally unqualified to practice CAM. Safety aspects will accordingly be based on a potential of unlike skills and knowledge level for CAM practitioners in Europe.

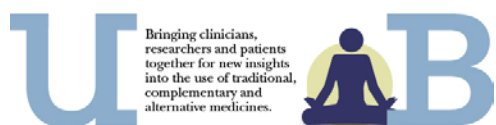
The established monitoring systems with regard to adverse reactions is mainly tailored to pharmaceutical drugs, and CAM supplements are therefore monitored for safety in a very rudimentary way.

Discussion and issues for workshop dialogue:

Our study so far shows that diversity is still the best word to describe the legislation/regulation of CAM in Europe. This impacts pan-European professional collaboration and development, patient access and safety as well as international clinical research collaboration.

The most important issue is **how European patients can be secured** safe and best quality health treatment when they choose CAM. With patients more willing to cross borders in their search for health care (encouraged by the recent Cross-border Health Directive), it is imperative that they are aware of the different

PLEASE NOTE: These discussion papers have been prepared for this conference and should not be circulated to non-delegates. In addition they should not be cited without written permission from the authors.



Supported by
wellcometrust

status of CAM in culturally similar European nations. In the current situation the most important issue that can assist patients is an easily accessible source of information. When they cross European borders for CAM treatment, they need to be aware of the potential substantial differences in professional background of apparently identical professional CAM providers in the European countries. They also need to be aware of varying reimbursement systems and how they are safeguarded if the treatment results in unwanted adverse or side effects.

Health authorities throughout Europe need to discuss how the safety of their patients can be safeguarded under the current regulatory system in Europe. The supervision systems used for conventional medicine may be ineffective and even inappropriate when monitoring the CAM field. Before passing further regulations of CAM practices, both national authorities and EU should generate specific knowledge on how the current regulations influence patients' safety when using CAM treatments.

Another issue is **professional collaboration and development**. When CAM professions in some countries are tightly regulated while the same professional categories in other countries are totally unregulated, common ground is difficult to be established between "colleagues". A licensed acupuncturist in Hungary will have considerable challenges in relating to a "colleague" in Norway practicing the profession on the basis of three weekend courses 10 years ago. How is it feasible to facilitate cross-border professional development under the current regulatory system in Europe, and what would the advantages and disadvantages be for **practitioners** if CAM were regulated at an EU/EEA level? These questions should be discussed within professional organizations in CAM before any further EU legislation is considered. Since the regulation of CAM professionals in many countries closely resembles the regulation of conventional health professionals the issue must be discussed with a comprehensive focus.

A third important issue is **clinical research collaboration**. Research on efficacy and effectiveness of CAM is severely hampered by this 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. Research should be strengthened on the monitoring and safety aspects on CAM practices. An essential discussion to be initiated is how to develop the current regulatory system in Europe to improve and facilitate cross-border clinical CAM research, and what would the advantages and disadvantages be for **researchers** if CAM were regulated at an EU/EEA level?

The legislation/regulation currently in place at a national level for conventional medicine has been largely used as a blueprint for CAM legislation/regulation. Whether this is an appropriate choice should be evaluated thoroughly. One important issue is whether Europe should follow the Far East where parallel legislation/regulation systems are established for conventional medicine and "traditional medicine", or whether it would be best to incorporate all health-related treatment practices in one single system of legislation/regulation.

Finally, legislation and regulation is seen as an important instrument to ensure a safe practice of treatment. The attractiveness of CAM can for many patients be seen as seeking something outside of the "establishment". This is in line with the postmodern partial distrust of the rationality of the past. If currently used CAM treatments are regulated into the "establishment", patients might still be inclined to seek the alternative, having options that might be even more ineffective and risky. "Over-regulating" CAM practices

PLEASE NOTE: These discussion papers have been prepared for this conference and should not be circulated to non-delegates. In addition they should not be cited without written permission from the authors.



Supported by
wellcometrust

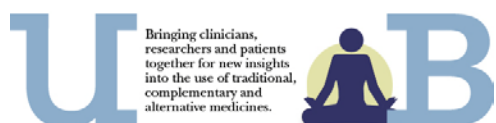
could consequently possibly endanger patient safety.

There is still a considerable knowledge gap in factors of high importance when making political choices about CAM legislation and regulation across Europe. Of special and urgent importance is to clarify advantages and disadvantages for **patients/practitioners/researchers** of regulating CAM at an EU/EEA level.

References:

- 1 The Parliamentary Assembly, *Resolution 1206 (1999) A European approach to non-conventional medicines*, in *Resolution 1206(1999)*, 22/03/11, 10.36. 1999, Parliamentary Assembly, Standing Committee, The European Union: Brussels.
- 2 The European Parliament and The European Commission, *DIRECTIVE 2011/.../EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on the application of patients' rights in cross-border healthcare*, in *2008/0142 (COD) PE-CONS 6/11*. 2011, The European Union: Brussels.
- 3 Ersdal, G. and CAM-CANCER consortium, *How are European patients safeguarded when using complementary and alternative medicine (CAM)? Jurisdiction, supervision and reimbursement status in the EEA area (EU and EFTA) and Switzerland*, in *Report CAM 21.11.05-1.doc*. 2005, NAFKAM, University of Tromsø: Tromsø. p. 1-53.

PLEASE NOTE: These discussion papers have been prepared for this conference and should not be circulated to non-delegates. In addition they should not be cited without written permission from the authors.



Supported by
wellcometrust

Attachment 3: Template example – the description of Romania

1.1 Romania

Romania has been a member of the European Union since 1 January 2007(1). Romania became a member of the Council of Europe in 1993(2).

1.1.1 The legal and regulatory status of CAM and CAM practices

In 2005 and 2007 national CAM legislation was introduced and from 2007 adjusted to EU Directives and Regulations. The new classification of occupation issued by order of the government 1832/2011 includes for the first time the denomination “non-MD associate practitioners of CAM”(3).

From 2007 citizens' rights and access to CAM therapies are regulated by “Law on Complementary and Alternative Medicine **nr. 118/2007**” (4). The law regulates the activities and practices of Complementary and Alternative Medicine for the prevention of illnesses and the promotion of health, healing of diseases and optimization of the human health from the biopsychosocial and spiritual points of view(4, 5).

According to chapter III, Art.16 in the Law on CAM nr 118/2007(4) all persons have free access to the treatments and practices of complementary and alternative medicine, regulated according to the law. Law nr.118/2007 states that patients receiving CAM treatment must receive information, preferably written, accessible and easy to understand of the benefits and risks of CAM treatment(3). CAM therapies legally practised in Romania are grouped in pharmacologic and biological therapies, herbal practice, diet-nutrition and lifestyle, alternative therapies, manual therapies, energetic and bio-electromagnetic applications. The therapy group “**alternative therapies**” includes among others **acupuncture, homeopathy, naturopathy, ayurveda and Chinese medicine**(3). Among others the group “**manual therapies**” includes **chiropractic, osteopathy and massage**.

In 2005 the Ordin nr. 418/2005 National Catalogue of Programmes for CAM studies was established. The studies were organized, according to Art I, in order to certify the competence of medical doctors, dentists and pharmacists and the methodological standards for its organisation and progress(5, 6). CAM studies included were among others acupuncture, homeopathy phytotherapy and apitherapy.

According to the Ordin nr. 418/2005 “Certification of graduation in the programme of complementary studies implied obtaining a competence issued exclusively by the Ministry of Health through the National Center of Continuous Education Bucharest only for medical doctors, dentists and pharmacists”(6).

Only medical doctors (MDs), dentists and pharmacists are allowed to practise **acupuncture, homeopathy, apitherapy, phytotherapy, chiropractic, osteopathy and TCM**. CAM practices are regulated by the Ministry of Health (7) and the CAM professions are recognized as an additional qualification for medical doctors(8). “In order to become a practitioner of

complementary/alternative medicine, the persons (medical doctors, dentists, pharmacists, psychologists) are obliged to add the specific competence obtained (acupuncture, phytotherapy, homeopathy..), with the approval of the National Center of Continuous Education for Medical Doctors, Dentists and Pharmacists Bucharest(4) on the authorization of free practise provided, according to the law, by the Ministry of Public Health". CME is not obligatory for approved CAM therapy doctors(8).

According to the CAM Medical Practitioners Order specialized committees for certain areas of practice (e.g. **acupuncture, herbal therapy, homeopathy, apitherapy**) will regulate professionals(6).

"In medical schools or faculties of pharmacy, students can take optional courses in **homeopathy, phytotherapy or acupuncture**, but none of the CAM modalities are taught in the core curriculum. Attempts are being made to arrange postgraduate courses in integrative medicine, accredited by the Romanian College of Physicians and addressed mainly to general practitioners"(7).

Romanian national CAM law on patients' rights complement the formulations given in the 2011/24/EU Directive on the application of patients' rights in cross-border healthcare(7, 9).

"Practitioners without a diploma of MD, dentist or pharmacist are authorized to practise CAM therapies (except those allowed only to MDs) after a short special training accredited by the Ministry of Health"(7).

We found no CAM professions registered for Romania in the EU regulated professions database (Directive 2005/36/EC)(10).

1.1.2 The governmental supervision of CAM Practices

Supervision and practice control activities of CAM in Romania is regulated by the law on professional organizations of medical practitioners of CAM (3).

- With the Medical Practitioners Order, CAM specialized committees for each area of practise of CAM, are bound to regulate professional practitioners in the specific area.
- The Order of Practitioners of CAM is required to develop code of ethics, supported by specialist committees. Code of ethics includes the rights to practise, disciplinary sanctions for professional incompetence, practise restrictions in case of incompatibility or damage to patient health.
- A register of practitioners of CAM is held at the headquarters of the Order of Practitioners of CAM, communicating with the National Centre for Training in Healthcare.
- The Ministry of Public Health, College of Physicians in Romania, Dental College and College of Pharmacists in Romania shall, in consultation with the Order of Practitioners of CAM, approve studys curricula for institutions that prepare practitioners of CAM to ensure level qualification.

- The Ministry of Public Health and the National Training Center in Healthcare, Department of CAM directs and controls activities in the field, including professional training for practitioners of CAM. Department of CAM supplies and accredits training programs for practitioners of CAM(3).

1.1.3 The reimbursement status of CAM practices and medicinal products

CAM treatment and medicinal costs are partially covered for acupuncture, homeopathy, phytotherapy and psychotherapy (House of National insurance of Health)(8, 11). Since 2010 manual therapies are not covered anymore due to the economic crisis in Romania(3).

1.1.4 Acupuncture

Acupuncture is legally recognized as a CAM therapy in the group “alternative therapies” in the law on CAM 118/2007(4).

Only medical doctors, dentists and pharmacists with approved additional qualification are allowed to practise acupuncture in Romania(6). A specialized committee for acupuncture regulates the profession (NATL)(6).

In medical schools or faculties of pharmacy students can take optional courses in acupuncture(7).

There is a professional society of acupuncture that has annual national congresses. There is a National Institute of research in CAM in Bucharest; its present director is also the president of the Romanian association of Acupuncturists(3).

There is no professorial chair for CAM therapy in Romania, but there are clinics of acupuncture in some faculties of medicine and hospitals of education and research(8).

1.1.5 Anthroposophic medicine

In Romania diplomas for anthroposophic doctors are not recognized. Postgraduate training courses in anthroposophic medicine are provided at private teaching centers(11). “The national associations of anthroposophic doctors require their members to complete significant numbers of hours of CME in anthroposophic medicine”(11).

1.1.6 Ayurveda

Ayurveda is legally recognized as a CAM therapy in the group “alternative therapies” in the law on CAM 118/2007(4).

There is a course that provides accredited qualifications in Ayurveda organized by the NATL Center for Training in Health care. Only MD’s, dentists, nutritionists can participate(3).

1.1.7 Chiropractic

Chiropractic is legally recognized as a CAM therapy in the group “manual therapies” in the law on CAM 118/2007(4).

Only medical doctors, dentists and pharmacists with approved additional qualifications are allowed to practise chiropractic in Romania(6). The therapists allowed to practise specialized kinetic therapies are called kinetherapists in Romania (see other treatments)(3).

1.1.8 Herbal medicine/Phytotherapy

Herbal therapy is legally recognized as a CAM therapy in the group “herbal practice” in the law on CAM 118/2007(4).

Only medical doctors, dentists and pharmacists with approved additional qualification, minimum a one year course with a diploma of competences, are allowed to practise phytotherapy in Romania (6). A specialized committee for herbal therapy regulates the profession(6) and there is an association of MD phytotherapists. ANATECOR (national association for CAM therapies) organizes courses of herbal therapies for practitioners, and the courses are approved by the Ministry of Labour(3).

In medical schools or faculties of pharmacy students can take optional courses in phytotherapy(7).

1.1.9 Homeopathy

Homeopathy is legally recognized as a CAM therapy in the group “alternative therapies” in the law on CAM 118/2007(4).

Homeopathy has historically from 1981 and 1995 been recognized by law as a distinct therapeutic system in Romania. Practise has been limited to medical doctors with specific homeopathic training(11).

Only medical doctors, dentists and pharmacists with approved additional qualification are allowed to practise homeopathy in Romania(6). A specialized committee for homeopathy regulates the profession(6) and, both by law and by the medical association, homeopathy is recognized as a medical specialty(6, 11). Diplomas of homeopathic doctors are approved by the government according to law and regulations(6, 11).

In medical schools or faculties of pharmacy students can take optional courses in homeopathy(7). Postgraduate training courses in homeopathy for doctors are provided at universities and homeopathy is an official part of the Continuous Education Programme for doctors (6, 11). Homeopathic doctors’ associations require a number of obligatory CME for their members(11).

1.1.10 Massage

Massage is legally recognized as a CAM therapy in the group “manual therapies” in the law on CAM 118/2007(4).

Massage courses are offered by training providers authorised by CNFPA – Consiliul National de Formare Profesionala a Adultilor. Participants to the courses are awarded with a Certificate, recognized by the Ministry of Labour, Family and Social Protection and Ministry

of Education, Youth and Sports. The Certificate will be accompanied by a transcript explaining the professional competencies acquired(3).

Certificates awarded for the courses enjoy professional recognition, according to law (OUG 129/2000 Republished) and can be registered in the Employment Record for the relevant professional occupation, based on the Classification of Occupations in Romania (COR)(12).

Further qualifications can be obtained, as detailed on the website of the Association of Professional Masseurs, www.maseuri.ro/useful/certified.php(3).

1.1.11 Naprapathy

We have not found legislation on naprapathy in Romania.

1.1.12 Naturopathy

Naturopathy is legally recognized as a CAM therapy in the group “alternative therapies” in the law on CAM 118/2007(4).

1.1.13 Neural therapy

We have not found legislation on neural therapy in Romania.

1.1.14 Osteopathy

Osteopathy is legally recognized as a CAM therapy in the group “manual therapies” in the law on CAM 118/2007(4).

Only medical doctors, dentists and pharmacists with approved additional qualification are allowed to practise osteopathy in Romania(6).

1.1.15 Traditional Chinese Medicine (TCM)

Chinese medicine is legally recognized as a CAM therapy in the group “alternative therapies” in the law on CAM 118/2007(4).

Only medical doctors, dentists and pharmacists with approved additional qualification are allowed to practise TCM in Romania(6).

1.1.16 Other treatments (mentioned if found in legislation)

Physiotherapy/Kinetotherapy (physiotherapy/chiropractic) is a regulated profession in Romania with the title “**Kinetoteraput**”. The title and the professional activity are protected by the state. The rules of professional conduct are determined directly by the state through national legislation. The physiotherapist must be state registered and obtain a licence to practise(13). Kinetotherapists have a higher education, usually 3 or 4 years. The law regulating kinetotherapy was issued in December 2009. The profession is regulated by the National Order of Kinetotherapists. <http://kinetoprofesional.blogspot.com/2009/03/proiect-lege-al-ordinului.html>(3). Romania has established a code of ethics for physiotherapists. The national authority responsible for the physiotherapy profession in Romania is the Romanian Federation for Physical Therapy (FRAK)(13).

1.1.17 References

1. EUROPA. Gateway to the European Union; member countries. Brussels EUROPA Communication department of the European Commission; 2011 [cited 2011 November 3]; Available from: http://europa.eu/about-eu/countries/index_en.htm.
2. Council of Europe. Council of Europe. Strasbourg: Council of Europe; 2011 [cited 2011 November 7]; Available from: <http://www.coe.int/lportal/web/coe-portal>.
3. Dragan S. Email: Legislation of CAM in Romania. Timisoara: University of Medicine and Pharmacy Victor Babes, Romania; 2011.
4. Law nr. 118/2007 privind organizarea și funcționarea activităților și practicilor de medicină complementară/alternativă (Concerning the organisation and functioning of the practices of complementary/alternative medicine), The Parliament of Romania(2007).
5. ECH (European Committee for Homeopathy). ECH in European Countries. Brussels: ECH; 2011 [cited 2011 September 12]; Available from: <http://www.homeopathyeurope.org/countries>.
6. Ordin nr. 418 din 20/04/2005 for the approval of the National Catalogue of Programmes for Complementary studies organised to certify the competence of medical doctors, dentists and pharmacists and the methodological standards for its organisation and progress., Parliament of Romania(2005).
7. CAMbrella. CAMbrella news. München: CAMbrella; 2011 [cited 2011 November 03]; Available from: <http://www.cambrella.eu/home.php?il=1&l=deu>.
8. Hegyi G. Questionnaire about the status of CAM therapies Romania. 2011.
9. DIRECTIVE 2011/24/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 9 March 2011, on the application of patients' rights in cross-border healthcare (OJ L 88, 4.4.2011, p.45), (2011).
10. The European Commission. Regulated professions database. Brussels: EUROPA; 2011 [cited 2012 February 10,]; Available from: http://ec.europa.eu/internal_market/qualifications/regprof/index.cfm?fuseaction=regProf.index.
11. CAMDOC Alliance ECH ECPM ICMART and IVAA. The regulatory status of Complementary and Alternative Medicine for medical doctors in Europe. Brussels 2010 January 2010. Report No.: 2010.
12. COR - Noua Clasificare a Ocupatiilor din Romania - ordinul 1832/2011, (2011).
13. Romanian Federation for Physical Therapy (FRAK). Physiotherapy in Romania. The World Confederation for Physical Therapy (WCPT) 2012 [cited 2012 March 19]; Available from: <http://www.physio-europe.org/index.php?action=15&subaction=details&member=40>.

Attachment 15.4. Template for country emails and telephone calls.

Dear XXX

I have received your address from XXXXX, and I really hope for your help. **Alternative additions:** (As I understand you are the one that have filled the questionnaire about CAM in your country, which I have received from XXX). (I am sorry I do not know anything more about you, however that can be filled out later).

We are planning an information travel from Tromsø, Norway to XXX from “date, time”. Hopefully we are able to have meetings with people that know well the legislation of Complementary and Alternative, traditional medicine in your country. As I understand you have contacts in the MOH and can arrange meetings with representatives.

So for the background story:

I am reviewing how CAM (Complementary and alternative medicine) is regulated and included in legislation in Europe. We have insufficient information from some of the European countries, included XXX (country).

NAFKAM at the University of Tromsø, Norway is a partner in the EU research programme CAMbrella where we are heading the Work Package 2 – legal questions.

<http://www.cambrella.eu/home.php> home site

<http://www.cambrella.eu/home.php?il=69&l=deu> legal WP

XXX (is a member of our Work Package group about legislation for CAM in European countries, or member of XXX CAM association) and has given me your address.

I would really appreciate making contact with expertise in this question in your country. It would be of great help if you could please forward this inquiry to the right persons and help me to arrange for meetings.

It could be of interest to make an appointment in The Ministry of Health in XXX (country). Contacts who know about CAM legislation/regulation is of great interest.

Our focus is:

- - 1 The legal status of CAM
- - 2 The regulatory status of CAM practices
- - 3 The governmental supervision of CAM practices
- - 4 The reimbursement status of CAM practices and medicinal products
- - 5 The regulation of CAM medicinal products

Secondary I am very interested in documents describing the issues. The documents have to be translated into English- or a summary in English with the original language as attachment with reference information.

I really hope you can help me

Yours sincerely

Solveig Wiesener

Senior Adviser

NAFKAM : National Research Center for Complementary and Alternative Medicine University
of Tromsø, Tromsø, Norway

http://www2.uit.no/ikbViewer/page/ansatte/organisasjon/hjem?p_dimension_id=88112&p_menu=42374&p_lang=1

Mobile: +47 90518648

Email: solveig.wiesener@uit.no

Attachment 15.5 Template: Interview and description for each country and treatment

The legal and regulatory status of CAM and CAM practices

- Legal connection to EUEFTA/EEA and Council of Europe
- CAM general legislation
- Specific treatment (one excel sheet for each treatment) regulation
- EU title (Directive 2005/36/EC)
- Regulated profession/ protected title
- Statutory register
- Medical Doctors (MDs) may practise
- Medical Doctors with CAM training may practise
- Conventional practitioners (CPs) (PS3 post-secondary level 3-4 years) may practise
- Conventional health personnel with CAM training may practise
- CAM practitioner (CAM trained personnel, medical trained, DSE diploma post-secondary education level) may practise
- Others may practise
- Other CAM legislation
- Notes

Check list for questions, definitions, terminology and clarifications:

CAM Legislation

The legal status of CAM treatments and practices are mostly regulated through

- Laws and governmental regulations on health care (conventional and CAM)
- General CAM legislation by law or governmental regulation
- Regulation of specific CAM practices and treatments
- No CAM specific legislation or regulation

CAM practices and treatment could also be regulated through other laws and regulations like criminal code, education, social security, finance and reimbursement regulations.

One issue is if the practitioner has a protected title either through EU Directive 2005/36/EC(1) on recognition of professional qualifications or as a national protected title in the specific country.

The level of education and training could be statutory regulated or voluntary. Some of the European Associations for doctors or CAM practitioners have developed guidelines to be followed for their members. We will also find regulations of governmental registries which could be statutory, voluntary and/or included in the membership of the different associations.

The national CAM/health legislation and regulation consists mostly of guidelines for permission or restriction to treat patients with the specific CAM treatment. This consists of

educational and/or training requirements and systems for authorizations and licenses. Requirements for registers and self-regulation are often included in the regulation of the practices. Self-regulation is mostly divided into statutory or voluntary requirements.

CAM Practices

Regulation of practices is mostly connected to formal education and/or training in conventional or non-conventional medicine. This is mostly divided into the following way:

A. Medical Doctors (MDs)

We have found different classifications: Medical doctor, medical doctor with CAM education, medical doctor with CAM licence, medical doctor with CAM authorization, physician, CAM physician, Allopathic doctor, non-allopathic doctor. In our report we will divide into Medical doctor (MD) and CAM MD (medical doctors with CAM training may practice).

B. Health professionals

In most cases this is conventional health personnel with an educational level of 3-5 years. Nurses and midwives are the most common professions. We will also find chiropractor, physiotherapist, veterinary, dentist a.o. in national legal documents, but differently regulated either as health personnel or CAM practitioners. We have found classifications as CAM practitioner, medical trained personnel, health professional, health practitioner, and others.

In our report we will divide into Practitioner or CAM practitioner. The latest has additional CAM training. Medical doctors will be included in this category if regulation includes both A and B.

C. Non-conventional practitioners

This will include practitioners with short or no medical training and CAM practitioners without conventional health education. Classifications could be: Medical trained personnel (level under 3 years), non-medical personnel, paramedics, non-professional health worker, acupuncturist, herbalist, homeopath, osteopath, naprapath, physiotherapist, etc.

Summarized we will divide CAM practices into:

- ❖ Medical doctors (MDs): Medical doctors may practice.
- ❖ Medical doctors with CAM: Medical doctors with CAM training may practice.
- ❖ Conventional practitioner: Conventional practitioners (CPs) (PS3 post-secondary level 3-4 years may practice (included MD's)).
- ❖ Health professional with CAM: Conventional health personnel with CAM training may practice (included MD's).
- ❖ CAM practitioner: CAM trained personnel, medical trained, DSE diploma post-secondary education level) may practice.
- ❖ Others: Others may practise.

Questionnaire about the status of CAM therapies ("CAMbrella" Project, EU FP 7)

NAME OF YOUR COUNTRY: ROMANIA

NAME OF THE CAM THERAPIES: /more could be listed/

XMedical Acupuncture/ TCM/X

Anthroposophic Medicine/X

Homeopathy/ Naturopathy/X

Ear AcupunctureX/

Manual Medicine (Osteopathy,Chiropraxy)/X

Phytotherapy /X

Bioresonance therapy/X

Reflexotherapy, Antroposophic Medicine, X

Ayurveda Medicine, Mind and Body techniques/ Neuraltherapy, Healing Touch/X

Alternative massage-moving techniques/XTuina//...../.....

Please circle the correct answers and feel free to add any information for further clarification.

More answers are possible.

1. RECOGNITION

1.1. Is your CAM therapy recognized in your country?

xa. Yes, recognized by law

xb. Yes, recognized by national medical association/chamber/council

c. Yes, recognized by national institute of medico-legal affairs

d. No

1.2. Is the profession of this CAM therapy recognized in your country?

a. Yes, as a medical specialty

Xb. Yes, as an additional qualification for medical doctors

c. Yes, as an additional qualification for veterinary surgeons

d. Yes, for other professionals without a full medical or veterinary education (non-medical therapists/practitioners)

e. Yes, otherwise, as follows:.....

f. No

Questionnaire about the status of CAM therapies

Reference of official document: there are specialized courses, in acupuncture, phytotherapy, homeopathy which are held at the Centre of postuniversity specialization in Bucharest, Romania.....

2. QUALIFICATIONS

2.1. Are there any official qualifications for doctors in this CAM therapy?

a. Yes, as a medical specialty

b. Yes, diplomas are issued by the national medical association/chamber/council

Xc. Yes, diplomas are issued by a national doctors association of this CAM therapy and recognized by the government

d. Yes, diplomas are issued by a national doctors association of this CAM therapy and recognized by the national medical association/chamber/council

Xe. Yes, otherwise, namely recognized direct by Ministry of Health

f. Diplomas are issued by a national doctors association of this CAM therapy, but not recognized by the government or the national medical association/chamber/council.

g. No qualifications at all.

2.2. Are there any official qualifications for non-medical therapists of this CAM therapy?

a. Yes, diplomas are issued by a national association of therapists and recognized by the government

b. Yes, otherwise, namely

c. Diplomas are issued by a national association oftherapists, but not recognized by the government.

d. No qualifications at all.

Xe. only medical doctors are authorized for acupuncture, homeopathy and phytotherapy.

3. TRAINING AT UNIVERSITIES

3.1. Is CAM therapy part of the undergraduate medical curriculum in your country?

a. Yes, as a separate subject

Questionnaire about the status of CAM therapies

- b. Yes, as a part of a course on Complementary and Alternative Medicine.
- c. Yes, as a part of Traditional Chinese Medicine (in case of acupuncture)
- d. Yes, it is obligatory for medical students
- Xe. Yes, it is optional for medical students
- f. No

3.2. How are postgraduate training courses in this CAM therapy for doctors provided in your country?

- a. At universities and hospitals of education and research
- b. At private teaching centers
- c. At both
- d. At none
- Xe. As a part of the official Continuous Education Program for Doctors

3.3. Is there a professorial chair for this CAM therapy in your country?

- a. Yes, at the university/ies of
- b. Yes, a chair shared with other CAM therapies at the university/yes of.....
.....
- d. If shared with other CAM therapies, please mention them here:
.....

Xe. No. But, there are clinics of acupuncture in some faculties of medicine and hospitals of education and research

4. CME (CONTINUING MEDICAL EDUCATION)

4.1. Is CME in general (conventional) medicine obligatory for all medical doctors in your country?

- Xa. Yes, is controlled by the government
- b. Yes, is controlled by the national medical association/chamber/council
- c. Yes, is controlled by the national doctors association of this CAM therapy
- d. Required number of hours per annum:
- e. No

4.2. Is CME in your CAM therapy obligatory for doctors in your country?

- a. Yes, is controlled by the government
- b. Yes, is controlled by the national medical association/chamber/council
- c. Yes, is controlled by the national doctors association of this CAM therapy
- d. Required number of hours per annum:

Xe. No

5. INSURANCE COVERAGE

5.1. Are the fees for this CAM therapy treatment covered by any insurance?

- a. Yes, by the national health insurance system
- b. Yes, by additional private insurance companies
- c. Yes, complete coverage

Xd. Yes, partial coverage, namely the acupuncture,phytotherapy,homeopathy,(House of National insurance of Health).....

e. No

5. 2. Are the costs for medicines used in this CAM therapy covered by any insurance?

- a. Yes, by the national health insurance system
- b. Yes, by additional private insurance companies
- c. Yes, complete coverage
- d. Yes, partial coverage, namely acupuncture,phytotherapy,homeopathyX.....

e. No

6. COLLABORATION

6.1. Is there any kind of collaboration between different CAM therapies?

- a. Yes, regular meetings
- b. Yes, exchange of newsletters
- c. Yes, conferences
- d. Yes, other, namely.....

Xe. No

6.2. Is there any kind of collaboration between your CAM therapy and conventional medicine?

- a. Yes, regular meetings
- b. Yes, report in the national medical journals
- c. Yes, conferences
- d. Yes, other, namely.....

Xe. No

7. SOME NATIONAL FIGURES

7.1. What is the number of medical doctors in your country who practice this CAM therapy?

.... (a rough estimation is preferred to no answer at all)

7.2. What is the number of medical doctors in your country who have taken a full training curriculum in this CAM therapy, i.e. at the level recommended/required by your association?

..... (a rough estimation is preferred to no answer at all)

7.3. What is the number of doctors of this CAM therapy united in the national professional association(s)?

7.4. What is the number of veterinary surgeons in your country who practice this CAM therapy?

..... (a rough estimation is preferred to no answer at all)

7.5. What is the number of therapists in this CAM therapy in your country?

..... (a rough estimation is preferred to no answer at all)

7.6. What is the number of well-trained therapists of this CAM therapy in your country?

..... (a rough estimation is preferred to no answer at all)

7.7. Are there any official documents or scientific papers that describe the use of this CAM therapy or CAM in general in your country (number of patients, doctors and/or other practitioners)? If so, would you please mention some references?

Questionnaire about the status of CAM therapies

As far I know there are official documents which describe the use of the CAM therapies.,but I can not mentioned in what way.....

.....
.....
.....
.....
.....

Thank you very much for having taken the time to complete the questionnaire!
For your further information I will let you know about summary if any request!

contracted by
Dr. Hegyi Gabriella MD.PhD.
CAM Departm. of Med. Univ.PECS
Hungary

PORTUGAL

First Request

CAMBrella Data for Work Package 1 'Definition and Terminology of CAM'

Please, answer the following questions:

1. How is acupuncture perceived in your country?

a. As a treatment technique?

Inclusive moxibustion? Yes ___ No ___ Sometimes ___

b. Inclusive other traditional and modern medicine techniques? Yes ___ No ___

c. As part of a medical system (Traditional Chinese Medicine)? Yes ___ No ___ Don't know ___

d. As a medical system (Chinese Medicine)? Yes ___ No ___ Don't know ___

e. As part of conventional medicine? Yes ___ No ___ Don't know ___

2. How is medical acupuncture (*) perceived in your country?

a. As part of conventional medicine? Yes ___ No ___ Don't know ___

b. As a treatment technique?

Inclusive moxibustion? Yes ___ No ___ Sometimes ___

c. Inclusive other traditional and modern medicine techniques? Yes ___ No ___

d. As part of a medical system (Traditional Chinese Medicine)? Yes ___ No ___ Don't know ___

e. As a medical system (Chinese Medicine)? Yes ___ No ___ Don't know ___

3. How is TCM (Traditional Chinese Medicine) perceived in your country?

a. As a medical system? Yes ___ No ___ Don't know ___

b. As a medical system inclusive acupuncture? Yes ___ No ___ Don't know ___

c. As a medical system inclusive acupuncture and moxibustion? Yes ___ No ___ Don't know ___

d. As Chinese phytotherapy / herbal medicine / pharmacology? Yes ___ No ___ Don't know ___

e. As classic Chinese medicine (before 1949)? Yes ___ No ___ Don't know ___

f. As modern Chinese medicine (after 1949)? Yes ___ No ___ Don't know ___

g. As standardized Chinese medicine? Yes ___ No ___ Don't know ___

h. As an open universal system? Yes ___ No ___ Don't know ___



4. How is CAM (Complementary Alternative Medicine) perceived in your country?

- a. Different methods not (yet) or partly included in conventional medicine?
Yes No Don't know
- b. Different medical systems not (yet) belonging to conventional medicine?
Yes No Don't know
- c. Does acupuncture (with moxibustion etc), belong to CAM?
Yes No Don't know depends on whom is practicing
- d. Does TCM belong to CAM?
Yes No Don't know

* ICMART has only medical doctors as members

5. Which term is mainly used in your country?

	by physicians	by general population / patients
acupuncture	x	x
TCM		x

(make your choice)

6. Under which term is acupuncture and / or TCM summarized?

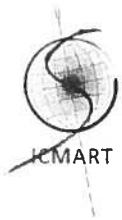
	acupuncture	TCM
CAM		
Alternative Medicine		
Integrative Medicine		
Traditional Medicine		
Biological Medicine		
Unconventional Medicine	x	x
Natural Healing		
Others		

(make your choice – you can put a cross beside several names)

Comments welcome, thank you!

Second Request

CAMBrella Data for Work Package 2 'Legal Status of CAM'



Topics of special importance:

1. the legal status of CAM / acupuncture in your country

Comments:

There is a law considering some unconventional therapies in the sense of regulation of the professionals which are not medical doctors. This law doesn't define the criteria for practice and curriculum of the professionals yet, waiting for the decisions of a Commission. This Commission is not working for the moment.

2. the regulatory status of CAM practices /acupuncture in your country

Comments:

Since 2002 the Medical Council included acupuncture as a medical degree. Until now, there is no regulation for the other professionals.

3. the governmental supervision of CAM practices /acupuncture in your country

Comments:

Just for medical doctors with degree on medical acupuncture.

4. the reimbursement status of CAM / acupuncture practices and TCM medicinal products in your country

Comments:

Just if it is done by medical doctors.

5. the regulation of CAM / TCM medicinal products in your country

Comments:

Not regulated

Attachment 15.8. CAMbrella population-based systematic literature review

Protocol Version 1.5

Table of contents

A	Preamble	1
B	Background	1
C	Objectives:.....	3
D	Literature search.....	4
E	Literature inclusion criteria	6
F	Literature exclusion criteria	7
G	Selection of studies.....	7
H	Assessment of study quality and risk of bias	8
I	Data extraction.....	8
J	References	17
K	Appendix I: Quality Assessment Tool ^[13]	19
L	Appendix II: MeSH terms exploded.....	22
M	Appendix III: Discussion and ensuing changes to this protocol	31

A Preamble

This protocol describes the planning details of a systematic review of studies in the prevalence of CAM in the 27 EU member states (Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Poland, Portugal, Slovakia, Slovenia, Rumania, Spain, Sweden and the United Kingdom) and 12 associated countries in FP7 (Albania, Bosnia & Herzegovina, Croatia, the Former Yugoslav Republic of Macedonia and Serbia, Iceland, Israel, Liechtenstein, Montenegro, Norway, Switzerland and Turkey). It is a work-in-progress document which will be amended during the course of the review when single steps can be planned in more detail or when modifications become necessary. Updated versions will receive a new version number and document the changes made. The purpose of this protocol is to provide consistency and standardisation in the review process. Critical issues will be resolved in discussion, with outcomes documented in this protocol.

B Background

The use of CAM has increased considerably in Western Countries over the last 20 years, evolving towards epidemiological, economical and politically importance for public health.^[1-4] There is an urgent need to address this area so that we can develop an understanding of the

issues surrounding CAM, its availability and its safe and legitimate provision to EU citizens. One of the many major drawbacks of existing nationwide surveys on CAM use is the lack of standardised terminology that limits reliable comparisons within and between EU member states. As a consequence an agreement in this field is essential across the EU so we can develop an understanding of what EU citizens utilise which CAM methods and how we should develop health policies in this area.

The patients' needs (WP4)

The use of specific CAM interventions such as acupuncture (Traditional Chinese Medicine), homeopathy, herbal medicine, massage, reflexology and Reiki healing has increased exponentially in Western industrialised nations countries over the last 20-25 years.^[1-3] CAM is mainly used in addition to conventional care for many chronic and some acute health conditions as well as for maintaining health.^[5,6] In comparison to conventional care, CAM treatment goals are often more focused on a detailed interest in patients' wellbeing in conjunction with recommendations concerning lifestyle and their quality of life. The WHO Centre for Health Development published a global atlas of traditional, complementary and alternative medicine by a text and map volume.^[4] The authors conclude that for the European region CAM is highly prevalent, but were unable to draw a clear picture of CAM use across the whole EU as the evidence available has been drawn from just a few EU member states.

The citizens' needs (WP3)

While WP4 further examines the perspectives of CAM users across the EU, WP3 begins to map the needs and attitudes of EU citizens regarding CAM more broadly. It explores questions such as: what are people's legal rights and/or consumer rights with respect to CAM? What are the general information needs about CAM, or the need for safety and quality control? What attitudes might people have towards CAM in general, the integration of CAM therapies into national healthcare systems or towards individual CAM therapies?

The providers' needs (WP5)

The provision and even the definition of various different types of CAM alter from country to country. For instance the provision of chiropractic therapies in Scandinavia is very much a part of routine medical care, whereas in some countries it has historically been practiced by healers in a regulated or unregulated manner. The use of acupuncture and Traditional Chinese herbal medicines have become increasingly popular throughout Europe with a variety of different and ill- coordinated national legislative frameworks governing use, provision, qualifications and registration of providers (practitioners or physicians) and the importation of medicinal products. This heterogeneity results in uncertainty for clinicians to

understand to whom they might legitimately refer and who might be considered an appropriate provider of CAM.

The researchers' needs (WP7)

Despite 10 -50% of the population using CAM, the only major EU initiative to develop a cogent national research policy for CAM has been as a consequence of the House of Lords report^[7] which promoted the development of the research capacity. This was a very successful but short-lived initiative. Extremely low funding levels of CAM research clearly fails to respond to the perceived patient need and the often ill informed debate that surrounds CAM provision.^[8] In addition, high quality scientific research demands a clear strategy based on consensus-based standardised terminology and understanding of prevalence in the population. This information is sorely lacking in the current literature and for the most part lacks adequate scientific quality.

Because of the integrative and often holistic nature of CAM therapies in comparison to conventional medicine, the framework of research and assessment strategies should also be consistent in evaluating this complex intervention.^[9-11]

The stakeholders' needs

As Europe becomes increasingly federalised and the healthcare provision of its citizens becomes a matter of both national and regional importance, providing safe cost-effective and clinically therapeutic CAM treatments becomes increasingly important. It is essential for all stakeholders, including consumers and providers, law and policy makers, as well as the CAM pharmaceutical industry, that we create an understanding of what is legitimate and safe practice, who should be providing it and whether it should be funded as a medical intervention.

C Objectives:

The initial phase of CAMbrella is a comprehensive evaluation of the of types of CAM and their respective terminology (WP1), what are the needs and attitudes of the citizens regarding CAM (WP3), who uses CAM (WP4), who provides CAM (WP5) and what research methods are used to identify population-based CAM prevalence and use (WP7) in EU39 (Figure 1).

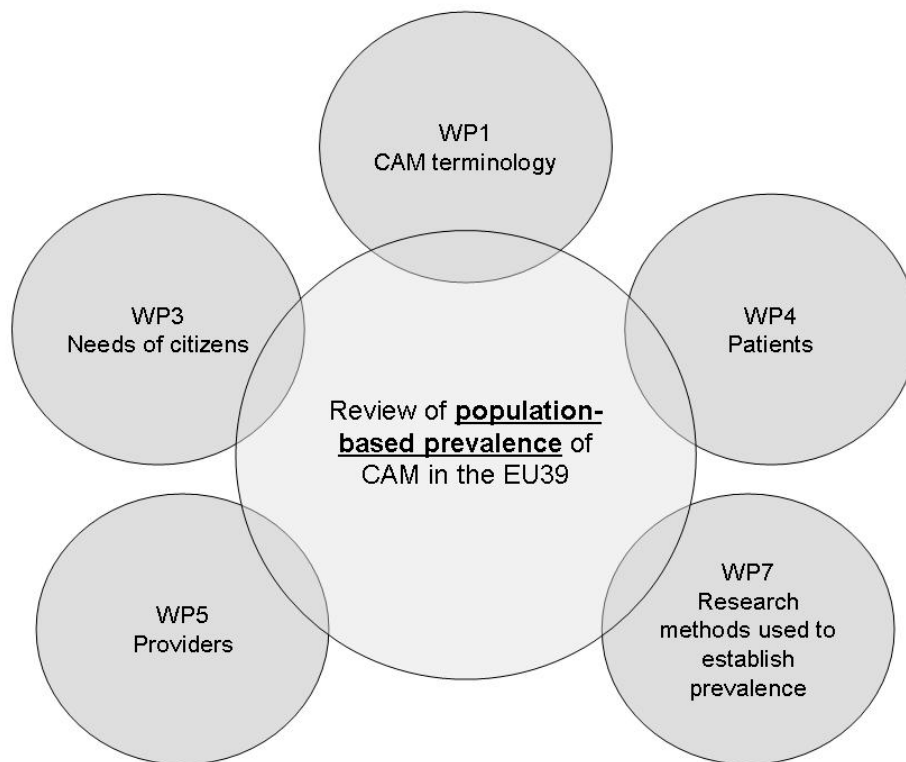


Figure 1: Aspects of CAM prevalence included in literature review

This review will collect (normally cross-sectional) population-based studies in 39 European countries which evaluate the prevalence of CAM in the above components.

Subsequent literature reviews in WP 7 will evaluate (a) research results (effectiveness, efficacy, cost-effectiveness, safety) in the main CAM therapies elucidated through this review and (b) concepts of CAM research methodology world-wide. Separate protocols for these literature reviews will be created. Together with input from expert opinion makers, these reviews will form a consensus-based road map for future CAM research.

D Literature search

We will concentrate our searches in the following databases:

1. Ovid MEDLINE
2. Cochrane Library
3. CINAHL
4. EMBASE
5. PsychINFO including PsychARTICLES
6. Web of Science
7. AMED
8. [CISCOM Database](#)

In addition, we will hand-search reference lists of included studies and request further potentially relevant publications from the personal files of CAMbrellians and other CAM experts. We will also conduct citation searches for all included studies, and search the reference lists of previously published reviews. A specific search protocol for grey literature will be developed by the University of Southampton and integrated into this search strategy.

a. Literature search terms

Limits	1. 01 January 1989 through 31 December 2009		
	2. Human studies		
Terms (MeSH or free text keywords when MeSH not accepted)			
	AND	AND	OR
Complementary therapies [MeSH exploded] [§]	Data collection [MeSH exploded] [§]	Europe [MeSH exploded] [§]	
Complementary medicine	Survey	Turkey	
complementary therap [*]	questionnaire	Israel	
alternatve medicine [*]	Epidemiology		
alternative therap [*]	Prevalence		
integrative medicine [*]	Needs assessment		
integrative therap [*]	Health services research [MeSH exploded] [§]		
unconventional medicine [*]	Demand		
unconventional therap [*]	Reason [*]		
Supplement [*]	Expectation [*]		
herbal	Motivation [*]		
homeopathy	Belief [*]		
osteopathy	Acceptance		
acupuncture	Value [*]		
traditional Chinese medicine	Philosophy		
mind-body therap [*]	World view		
Naturopathy	Public		
Meditation	Lay public		
Massage	Population		
Ayurveda	Consumer		
Chiropractic medicine	Access barriers		
Manipulation	Access trends		
Biofield therap [*]	Patterns of use		
Reiki	Barriers		
Therapeutic touch	Registration		
Yoga	Necessity		
aromatherapy	Requirement [*]		
prayer	Consumer choice		
XXX	Knowledge inclination		
	Approach		
	Outlook		
	Position		

Limits	1. 01 January 1989 through 31 December 2009		
	2. Human studies		
Terms (MeSH or free text keywords when MeSH not accepted)			
	AND	AND	OR
	Opinion		
	Point of view		
	Inhabitant*		
	Resident*		
	Frequency		
	Popularity		
	Predominance		
	Occurance		
	Incidence		
	Pervasiveness		

^ssee Appendix II

E Literature inclusion criteria

To be included in the review the studies **must** meet the following criteria:

1. Design:
 - a. Population-based study AND
 - b. Cohort study OR
 - c. Cross-sectional study
2. Participants:
 - a. Those receiving CAM therapies that are broadly consistent with NCCAM definition
 - b. in any EU39 country
 - c. all ages
 - d. assessment of at least one socio-demographic variable
3. Languages:
 - a. any EU39 language (may need to be modified, depending on availability of qualified translators)
4. Outcome:
 - a. Reports the prevalence of use in the general population of either:
 - i. CAM in general, or
 - ii. one or more specific CAM modalities

In addition, for specific literature reviews conducted by the relevant WP, the following inclusion criteria can apply

1. Health care needs assessment, safety and information needs, and attitudes towards CAM (for WP3)
2. Description of provider of CAM therapy (for WP5)
3. Statistical assessment of at least one health-related characteristic (for WP7)

F Literature exclusion criteria

1. non-peer-reviewed journal
2. non-cross-sectional or non-cohort studies
3. qualitative studies
4. editorial, letter, theses, dissertations, case study, congress abstracts
 - (1) **accepted** theses and dissertations may be included if they meet the inclusion criteria in E. above
5. unpublished and ongoing trials
6. presentation as abstract only
7. no abstract
8. double publication found in different databases
9. focus exclusively on CAM use in disease-specific populations (e.g. cancer)

G Selection of studies

An electronic database (Reference Manager or EndNote) will be used to maintain the search results. One reviewer will check all hits of the literature search and exclude clearly irrelevant articles based on titles and abstracts. Articles excluded at this stage are those not at all related to the **prevalence** of CAM use. The number of articles excluded at this stage will be recorded, but specific reasons for exclusion will not be recorded (beyond 'clearly irrelevant'). As some articles excluded for the prevalence review may in fact be appropriate for inclusion by the other WPs, the saved searches will be available to members of other WPs by requesting Sue Earley's (S.Eardley@southampton.ac.uk) log-in and password details. Titles, abstracts, and (if necessary) full text copies of all remaining articles will then be assessed by at least two reviewers independently for eligibility. Publications will be excluded only on agreement between the two reviewers. At this stage, reasons for excluding each article will be documented in the database, according to the exclusion criteria listed above. Disagreements will be documented and resolved by discussion (if necessary by a third reviewer). Inter-rater agreement will be calculated by Cohen's kappa. If several reports for a single study are published, all publications will be reviewed if they meet eligibility criteria. Full text copies of all eligible papers will be obtained and translated into English if necessary. This database and electronic copies of articles will also be made available to the other WPs.

H Assessment of study quality and risk of bias

To evaluate quality, a catalogue of 18 questions organised in 4 domains will be answered plus a section for overall comments raising important concerns (Appendix 1). The questions are weighted for importance for overall study quality by assignment of points. This quality assessment tool is based on the STROBE Statement checklist for observational studies ^[12] plus one item addressing conflict of interest and has been used in previous evaluations of CAM prevalence. ^[13]

Aspects of methodological and reporting quality will be assessed by at least two reviewers independently for a subsample of approximately 20% of the studies. Inter-rater agreement will be calculated by Cohen's kappa. Disagreements will be documented and resolved by discussion (if necessary by a third reviewer). If agreement on this subsample is low (<.9), the remaining 80% of studies will also be assessed by the second reviewer. The results will be presented in a table with each item listed with its points received plus a summary score.

I Data extraction

Each work package will be responsible for extraction of data pertinent to their topic. WP4 will extract **common variables** for all WP in addition to those for WP4 (i.e. variable 1-74). Two reviewers will extract information independently using a pre-tested standardised form specific for the respective review and work package. The second reviewer will extract information for a subsample of approximately 20% of the studies only. Inter-rater agreement will be calculated by Cohen's kappa. Disagreements will be documented and resolved by discussion (if necessary by a third reviewer). If agreement on this subsample is low (<.9), the remaining 80% of studies will also be assessed by the second reviewer. The following is an initial table of possible extraction variables and will be developed further by the WP teams.

Extraction variables

	Definition/Explanation	Values
Common variables for all WPs		
1. Study ID-Number	generated by reviewer	
2. Reviewer initials	Corresponding to list of names	
3. Title of publication	Full title of article	
4. Year of publication	Year article was published	Year
5. First author	First author's surname and first initial	
6. Journal title	Full title of journal	
7. Publication details of article	Journal issue Journal volume Article page numbers	
8. Place of research	Country where research conducted	

	Definition/Explanation	Values
9. Language of publication	Language that article was written in. Abstract must be in English	
10. Definition of CAM in paper	Type of CAM definition on which the research was based, as indicated in paper	(1) NCCAM (2) Cochrane collaboration (3) BMA (4) WHO (5) House of Lords (6) Eisenberg (1993) (7) Ernst & Cassileth (1998) (8) Zollman & Vickers (1999) (9) Other (describe)
11. CAM Definition	Direct quote of definition used in article	
12. Year of data collection	Year that data was collected (not year published nor year of diagnosis)	Year
13. Study objective	Direct quote from article of what the authors wanted to study	
14. Length of recruitment period	How long from initial questionnaire to establishment of sample population	
15. Ethical approval	Statement of whether the study had been approved by IRB or similar ethics committee	(0) not described (1) approved by ethical committee
16. Sampling method	Direct quote from article describing the sampling method	
17. Study design	Stated type(s) of study design in article	(1) cross-sectional (2) cohort study (3) multi-centre (4) single centre (5) other
18. Type of questionnaire used	State whether questionnaire was piloted (used in a small group, evaluated and changed if necessary before general use), validated (validity statistically analysed against other markers to corroborate results) etc.	(0) not stated (1) piloted (2) validated (3) based on previous questionnaire (4) non-validated questionnaire
19. Sample size	Number of participants: i.e. 100 questionnaires sent out and 80 returned, sample size is 80	
20. Participation rate	Response rate is the proportion (%) of people participating in study out of the selected study population. (e.g. if 100 questionnaires were	

	Definition/Explanation	Values
	sent out and 80 returned, the participation rate is 80%)	
21. Number of patients receiving CAM therapy	Number of patients receiving CAM therapy as proportion (% to 1 decimal) of total sample size. i.e if sample size was 80 and 45 people received CAM: 45/80, 56.3%	x/N (number of CAM patients/sample size), %
22. Age of whole sample*	The age range and/or mean age±standard deviation (SD) of <u>all participants in the sample</u> (=sample size) inclusive of 1 decimal point	Age range and/or mean age±SD (0) = not described
23. Age of CAM users*	The age range and/or mean age±standard deviation (SD) of <u>CAM users</u> inclusive of 1 decimal point	Age range and/or mean age±SD (0) = not described
24. Age of non-CAM users*	The age range and/or mean age±standard deviation (SD) of <u>non-CAM users</u> inclusive of 1 decimal point	Age range and/or mean age±SD (0) = not described
25. Gender of whole sample*	The fractions and % of male and female patients of <u>all participants in the sample</u> (N=sample size)	M: x/N, % F: x/N, % (0) = not described
26. Gender of CAM users*	The fractions and % of male and female patients of <u>CAM users</u> (n=CAM users)	M: x/n, % F: x/n, % (0) = not described
27. Gender of non-CAM users*	The fractions and % of male and female patients of <u>non-CAM users</u> (n=non-CAM users)	M: x/n, % F: x/n, % (0) = not described
28. Ethnicity of whole sample*	The different ethnicities of <u>all participants in the sample</u> listed with fraction and % of whole sample (N=sample size)	Ethnicity, x/N, % (0) = not described
29. Ethnicity of CAM users*	The different ethnicities of <u>CAM-users</u> listed with fraction and % of CAM users (n=CAM users)	Ethnicity, x/n, % (0) = not described
30. Ethnicity of non-CAM users*	The different ethnicities of <u>non-CAM-users</u> listed with fraction and % of non-CAM users (n=non-CAM users)	Ethnicity, x/n, % (0) = not described
31. Marital status of whole sample*	The different marital status of <u>all participants in the sample</u> listed with fraction and % of whole sample (N=sample size)	Marital status, x/N, % (0) = not described
32. Marital status of CAM users*	The different marital status of <u>CAM-users</u> listed with fraction and % of CAM users (n=CAM users)	Marital status, x/n, % (0) = not described

	Definition/Explanation	Values
33. Marital status of non-CAM users*	The different marital status of non-CAM-users listed with fraction and % of non-CAM users (n=non-CAM users)	Marital status, x/n, % (0) = not described
34. Education levels of whole sample*	The different education levels of all participants in the sample listed with fraction and % of whole sample (N=sample size)	Education level, x/N, % (0) = not described
35. Education levels of CAM users*	The different education levels of CAM-users listed with fraction and % of CAM users (n=CAM users)	Education level, x/n, % (0) = not described
36. Education levels of non-CAM users*	The different education levels of non-CAM-users listed with fraction and % of non-CAM users (n=non-CAM users)	Education level, x/n, % (0) = not described
37. Income levels of whole sample*	The different income levels of all participants in the sample listed with fraction and % of whole sample (N=sample size)	Income level, x/N, % (0) = not described
38. Income levels of CAM users*	The different income levels of CAM-users listed with fraction and % of CAM users (n=CAM users)	Income level, x/n, % (0) = not described
39. Income levels of non-CAM users*	The different income levels of non-CAM-users listed with fraction and % of non-CAM users (n=non-CAM users)	Income level, x/n, % (0) = not described
40. Employment status of whole sample*	The different employment statuses of all participants in the sample listed with fraction and % of whole sample (N=sample size)	Employment status, x/N, % (0) = not described
41. Employment status of CAM users*	The different employment statuses of CAM-users listed with fraction and % of CAM users (n=CAM users)	Employment status, x/n, % (0) = not described
42. Employment status of non-CAM users*	The different income levels of non-CAM-users listed with fraction and % of non-CAM-users (n=non-CAM users)	Employment status, x/n, % (0) = not described
43. Condition(s) treated with CAM	The different conditions and number of patients with this condition treated with CAM listed with fraction and % of whole sample (n=CAM users)	Condition treated with CAM, x/n, %
44. Length of condition treated with CAM	For each condition listed above, list number of years patients have had illness or condition	mean years±SD and/or range
45. Reasons for using CAM	The reasons mentioned in paper will	Reason for using CAM, x/n

	Definition/Explanation	Values
	<p>be listed with the number of CAM users who stated this reason. (n=CAM users). They will later be grouped into categories.</p> <p>Possible categories</p> <ul style="list-style-type: none"> - Cure illness - Complementary' - To avoid side-effects of conventional medicine - Treatment of side-effects of conventional medicine - For enhanced physician-patient interaction - Prevent recurrence of disease - Maintain good health/overall well-being - Boost immune system - Explore every treatment option - biomedical treatment ineffective or unsuccessful - Other (does not fit into any other category) <p>(1) Reason not given: Some papers may have participants who did not give any reason. The percentage and fraction of participants who did not give a reason will be under this category.</p> <p>(2) N/A: If the paper did not investigate the reasons for using CAM, the entire column is denoted with N/A</p> <p>The percentage is calculated from the number of CAM users who selected a reason divided by the overall number of CAM users. As one person could list more than one reason of CAM use, the total % could be >100%. (n=CAM users).</p>	<p>(0) not evaluated</p> <p>(1) Reason not given, x/n, %, N/A</p> <p>(2) N/A</p>
46. Reasons for not using CAM	<p>The reasons mentioned in paper will be listed with the number of non-CAM users who stated this reason. (n=non-CAM users). They will later be grouped into categories.</p> <p>(1) Reason not given: Some papers may have participants who did not</p>	<p>Reason for not using CAM, x/n</p> <p>(0) not evaluated</p> <p>(1) Reason not given, x/n, %, N/A</p> <p>(2) N/A</p>

	Definition/Explanation	Values
	<p>give any reason. The percentage and fraction of participants who did not give a reason will be under this category.</p> <p>(2) N/A: If the paper did not investigate the reasons for not using CAM, the entire column is denoted with N/A</p>	
47. Type of specific practitioner- or physician-prescribed CAM modalities used	List each modality that was prescribed or delivered by a practitioner or physician . A modality is defined as a technique of applying a therapeutic regimen or agent. ^[14]	
48. Setting where specific practitioner- or physician-prescribed CAM modality was delivered	For each practitioner- or physician-prescribed CAM modality listed above, list where the service was delivered, e.g. GP's office, hospital, integrated clinic, private clinic etc.	
49. Number (% of whole) of patients using specific practitioner- or physician-prescribed CAM modalities	For each practitioner- or physician-prescribed CAM modality listed above, list number of patients and % of whole sample of each practitioner- or physician-prescribed CAM modality (N=sample size). As one person could list more than one type of CAM modality, the total % could be >100%	x/N , %
50. Number (% of CAM-users) of patients using specific practitioner- or physician-prescribed CAM modalities	For each practitioner- or physician-prescribed CAM modality listed above, list number of patients and % of CAM users (n=number of CAM users). As one person could list more than one type of CAM modality, the total % could be >100%	x/n, %
51. Time period of specific practitioner-prescribed CAM modalities	For each practitioner- or physician-prescribed CAM modality listed above, list when the modality was used	(0) not stated (1) ever (2) in the past 12 months
52. Duration of CAM use of specific practitioner- or physician-prescribed CAM modalities	For each practitioner- or physician-prescribed CAM modality listed above, list for how long the modality was used	Number of months
53. Level of CAM use (Kristoffersen criteria ^[15])	Classification of patient's exposure to CAM	(CAM1): Seen a CAM practitioner at least 4 times (CAM2): Seen a CAM

	Definition/Explanation	Values
		<p>practitioner at least once (CAM3): Use of CAM provider, OTC-products or CAM techniques</p> <p>(CAM4): Use of a CAM provider, OTC-products, CAM techniques or special diets</p> <p>(CAM5): Use of a CAM provider, OTC-products, CAM techniques, special diets or exercise</p> <p>(CAM6): All CAM use including prayer</p>
54. Outcomes of specific practitioner-prescribed CAM modalities	For each practitioner- or physician-prescribed CAM modality listed above, list any evaluated outcome results	
55. Satisfaction of specific practitioner- or physician-prescribed CAM modality	For each practitioner- or physician-prescribed CAM modality listed above, list number of patients and % of CAM-users in each level of satisfaction (n=number of CAM users)	x/n in each level of satisfaction
56. Type of specific self-prescribed or purchased CAM modalities used	List each modality that was self-prescribed or self-purchased	
57. Number (% of whole) of patients using specific self-prescribed or purchased CAM modalities	For each self-prescribed or self-purchased CAM modality listed above, list number of patients and % of whole sample of each self-prescribed or self-purchased CAM modality (N=sample size). As one person could list more than one type of CAM modality, the total % could be >100%	x/N , %
58. Number (% of CAM-users) of patients using specific self-prescribed or purchased CAM modalities	For each self-prescribed or self-purchased CAM modality listed above, list number of patients and % of CAM users (n=number of CAM users). As one person could list more than one type of CAM modality, the total % could be >100%	x/n, %
59. Time period of specific self-prescribed or	For each self-prescribed or self-purchased CAM modality listed	(1) ever (2) in the past 12 months

	Definition/Explanation	Values
purchased CAM modalities	above, list when the modality was used	(3) not stated
60. Duration of CAM use of specific self-prescribed or purchased CAM modalities	For each self-prescribed or self-purchased CAM modality listed above, list for how long the modality was used	Number of months
61. Outcomes of specific self-prescribed or purchased CAM modalities	For each self-prescribed or purchased CAM modality listed above, list any evaluated outcome results	(0) not described
62. Satisfaction of specific self-prescribed or purchased CAM modality	For each self-prescribed or purchased CAM modality listed above, list number of patients and % of CAM-users in each level of satisfaction (n=number of CAM users)	x/n in each level of satisfaction
63. Other co-morbidities of patients	List any co-morbidities of patients	(0) not described
64. Use of conventional treatments with CAM	List any conventional medical treatments used for illnesses treated also with CAM	(0) not described
65. Use of conventional treatments for illness not treated with CAM	List any conventional medical treatments used for illnesses not treated with CAM	(0) not described
66. Key conclusions from authors	Direct quote of key conclusions	
67. Comments of author	Note any significant comments regarding limitations, etc. listed by author	(0) no comments
68. Study funding source	List the source of funding for the study, as stated by the authors	(0) not stated
69. Correspondence required	Note any necessary correspondence with author	
70. Reference to other studies		
71. Comments of reviewer	Any comments to study from reviewer	
72. Quality of study (based on evaluation Appendix 1)	Final % grade of quality	
73. Eligible for inclusion in review	Judgement of eligibility by reviewer	(0) no (1) yes
74. Reason for exclusion from review	List reason for exclusion from this literature review	(1) not population-based
Variables specific to WP1		
75. definition of CAM in manuscript	Same as 11	

	Definition/Explanation	Values
76. definitions and terminology of CAM therapies in manuscript	Same as 46 and 54	
77. Historical background to CAM definition	Historical connotation of CAM modalities as defined in manuscript	(0) not stated
Additional variables specific to WP3		
78. What information about CAM do citizens want and need?	List given types of information about CAM therapies e.g. safety, side effects, therapeutic value, registration	(0) not described
79. From whom do citizens access and want to get information about CAM?	List sources of information about CAM e. g. physician, nurses, CAM practitioner, Internet, national health boards, consumer councils, etc.	(0) not described
80. What type(s) of CAM therapies are desired and used?	List given types of CAM therapies described by patients as desirable and used	(0) not described
81. For what illnesses or conditions are CAM therapies desired?	List given illness or conditions for which CAM therapies are desirable and used	(0) not described
82. What attitudes do citizens hold about CAM?	List views on: CAM in general, individual CAM therapies, the integration of CAM into national health services, and training of CAM practitioners	
Additional variables specific to WP4		
83. Out-of-pocket (OOP) expenditure on CAM therapy	For each type of CAM modality listed above, list what patient paid OOP for CAM therapy, with currency	mean±SD and currency (0) not described
84. Health insurance expenditure on CAM therapy	For each type of CAM modality listed above, list what the health insurance paid for CAM therapy, with currency	mean±SD and currency (0) not described
85. Total cost of CAM therapy	For each type of CAM modality listed above, list total cost of CAM therapy and currency	mean±SD and currency (0) not described
86. Health insurance coverage of CAM	List whether CAM therapy was covered by health insurance	(0) not described (1) complete coverage (2) partial coverage (3) no coverage
Additional variables specific to WP5		
87. Type of practitioner or physician delivering treatment	For each type of CAM modality listed above, list type of practitioner or physician delivering treatment	(0) not described
88. Training of practitioner or physician	For each type of CAM modality listed above, list training of	(0) not described

	practitioner or physician delivering treatment	
89. Age of practitioner or physician	For each type of CAM modality listed above, list age of practitioner or physician delivering treatment	(0) not described
90. Gender of practitioner or physician	For each type of CAM modality listed above, list gender of practitioner or physician delivering treatment	(0) not described
91. Ethnicity of practitioner or physician	For each type of CAM modality listed above, list ethnicity of practitioner or physician delivering treatment	(0) not described
92. How CAM is provided	For each type of CAM modality listed above, list how and where the CAM therapy is delivered	(0) not described
Additional variables specific to WP7		
93. statistical methods used in analysis	List stated statistical methods used to calculate prevalence	(0) not described
94. Missing data	Describe whether missing data was imputed	(0) not described (1) imputed
95. Method of missing data imputation	Describe method of missing data imputation	(0) not described (1) method

*If results are reported separately for different groups (i.e. children/adults, men/women, etc), the following variables should be extracted for each individual group.

J References

- [1] Eisenberg DM, Davis RB, Ettner SL, Appel S, Wilkey S, van Rompay M, Kessler RC: Trends in alternative medicine use in the United States, 1990-1997 - Results of a follow-up national survey. *Jama-Journal of the American Medical Association* 1998, 280:1569-75.
- [2] Härtel U, Volger E. Inanspruchnahme und Akzeptanz klassischer Naturheilverfahren und alternativer Heilmethoden in Deutschland – Ergebnisse einer repräsentativen Bevölkerungsstudie. *Forsch Komplementärmed Klass Naturheilkd* 2004;11:327-34.
- [3] Molassiotis A, Fernandez-Ortega P, Pud D, Ozden G, Scott JA, Panteli V et al. (2005). Use of complementary and alternative medicine in cancer patients: a European survey. *Ann.Oncol.*, 16, 655-63.
- [4] Bodeker G, Ong CK, Grundy C, Burford C, Shein K. WHO Global Atlas of Traditional, Complementary and Alternative Medicine. WHO, Kobe, 2005.
- [5] Weis J, Bartsch HH, Hennies F, Rietschel M, Heim M, Adam G, Gartner U, Ammon A: Complementary medicine in cancer patients: Demand, patients' attitudes and psychological beliefs. *Onkologie* 1998, 21:144-9.
- [6] Mansky PJ, Wallerstedt DB. Complementary medicine in palliative care and cancer symptom management. *Cancer Journal*. 2006;12(5):425-31.

- [7] House of Lords Select Committee on Science and Technology. 6th Report, Session 1999-2000. Complementary and Alternative Medicine. 2000. Report No.: 6.
- [8] Lewith G. Funding for CAM. *BMJ* 2007;335:951.
- [9] Fønnebø V, Grimsgaard S, Walach H, Ritenbaugh C, Norheim AJ, MacPherson H, Lewith G, Launsø L, Koithan M, Falkenberf T, Boon H, Aickin M. Researching complementary and alternative treatments – the gatekeepers are not at home. *BMC Medical Research Methodology* 2007, 7:7 doi:10.1186/1471-2288-7-7.
- [10] Walach H, Flakenberg T, Fønnebø V, Lewith G, Jonas WB. Circular instead of hierarchical: methodological principles for the evaluation of complex interventions. *BMS Medical Research Methodology* 2006,6:29 doi:10.1186/1471-2288-6-29.
- [11] Craig P, Dieppe P, Macintyre S, Mitchie S, Nazareth I, Petticrew M. Developing and evaluating complex interventions: the new Medical Research Council guidance. *BMJ* 2008;337:a1655 doi: 10.1136/bmj1655.
- [12] Vandembroucke JP, von Elm E, Altman DG, Gøtzsche PC, Mulrow CD, Pocock SJ, Poole C, Schlesselman JJ, Egger M for the STROBE Initiative. Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) Explanation and Elaboration. *Epidemiology* 2007;(18)6:805-835.
- [13] Bishop F, Prescott P, Chan Y, Saville J, von Elm E, Lewith G. Prevalence of Complementary Medicine Use in Pediatric Cancer: A Systematic Review. *Pediatrics* (in press).
- [14] Jonas. *Mosby's Dictionary of Complementary and Alternative Medicine*. 2005, Elsevier.
- [15] Kristoffersen AE, Fønnebø V, Norheim AJ. Use of Complementary and Alternative Medicine Among Patients: Classification Criteria Determine Level of Use. *The Journal of Alternative and Complementary Medicine* 2008;14(8):911-919.