



Pan-European Research Network
for Complementary and
Alternative Medicine (CAM)

Legal status and regulation of CAM in Europe

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ECU - European Chiropractors' Union - Executive Council meeting

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CAM

Legal Status and Regulations

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Place

CAMBrella's Final Conference

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Bavaria to the European Union
Brussels, November 29, 2012

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Report 1: CAM regulations in the European countries

Report 2: Herbal and homeopathic medicinal products

Report 3: CAM regulations in EU/EFTA/EEA



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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

Regulation of health care in Europe

The EU has repeatedly confirmed that it is up to each member state to organize and regulate their health care system

CAMbrella WP2 Methodology

Data were collected from 39 countries by:

1. Communicating with the Ministries of Health, Law or Education, governmental representatives, and members of national CAM associations.
2. Searches in the national web sites/databases as well as EUROPA and EUR-lex to identify official legal documents.
3. Direct dialogue with European CAM associations/coalitions, CAMbrella members and stakeholders.
4. Face-to-face meetings with the Ministries of Health and CAM practitioners representing organizations

European CAM legislation



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



Acupuncture



Acupuncture

- 2 Regulated profession and EU registered
- 0 Regulated profession - not EU registered
- 25 Regulated treatment - not regulated profession
- 12 No therapy-specific regulation



Norwe
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Regulation of herbal medicinal products

Medicinal products are not defined as a part of health policy, and can therefore be regulated at the EU level.

The individual state within the EU/EEA area are therefore no longer free to uphold national regulation of medicinal products in violation of EU directives.

Homeopathy

- 1** Regulated profession and EU registered
- 2** Regulated profession - not EU registered
- 22** Regulated treatment - not regulated profession
- 14** No therapy-specific regulation



Homeopathy in Sweden

1. “Anyone” not authorized as health personnel can practice homeopathy
2. Health personnel are obliged to “carry out their work in accordance with science and proven experience”
3. BUT, Patient safety issues “trump” this obligation according to the Swedish Supreme Administrative Court

CAM regulation in EU

Two resolutions. Little happened!

The status of “non-conventional medicine”. Resolution A4-0075/97

The European Parliament Resolution on how non-conventional medicine should be included more formally as a special field in the European legislation.

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

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

EU Directives

1. Directive 2011/24/EU – Patients’ rights in Cross-border healthcare.
2. Directive 2005/36/EC Professional Qualifications
 - With the EC database of regulated professions.
3. Directive 2004/38/EC – The right to move and reside freely



Chiropractic

- 10 Regulated profession and EU registered
- 6 Regulated profession - not EU registered
- 11 Regulated treatment - not regulated profession
- 12 No therapy-specific regulation



Consequences for European patients

1. A wide diversity of available treatments and providers
 2. For similar conditions, different levels of care
 3. Different quality of services
 4. Unpredictable quality of services
 5. Limited access to services
- Every aspect of the current situation can be a threat to patient safety**

Consequences for European CAM practitioners

1. Serious concerns with regard to the predictability, quality and safety of CAM in Europe
2. The current situation can be a threat to patient safety and is very concerning

**The current situation
can be a threat to
patient safety**

Consequences for European CAM researchers

1. Practices and practitioners are not comparable across national boundaries
2. Any observational or experimental study will therefore be generalizable only within a narrow national or cultural context.

**This can be a threat
to patient safety**

Possible ways forward

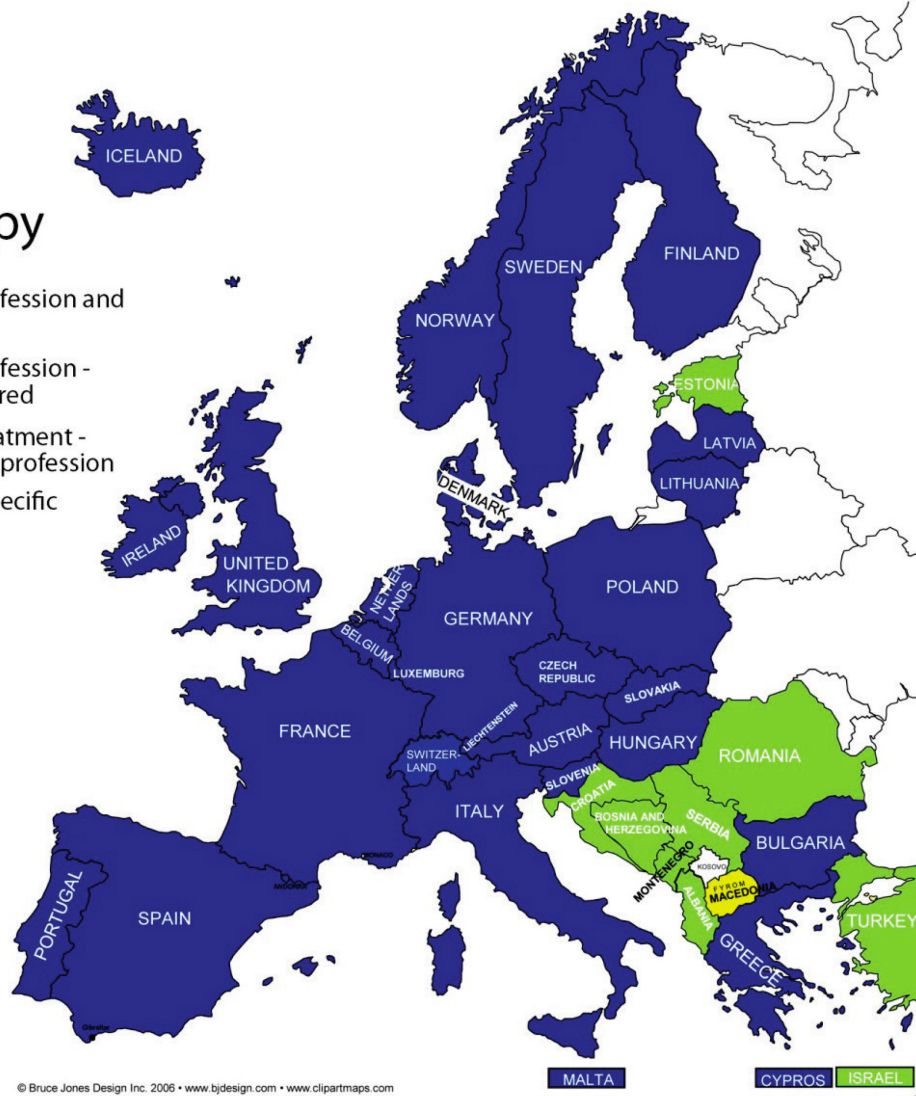
1. Legislation and regulation at the EU/EEA level
2. Voluntary harmonization.

**Voluntary
harmonization can be
done**



Physiotherapy

- 29** Regulated profession and EU registered
- 9** Regulated profession - not EU registered
- 0** Regulated treatment - not regulated profession
- 1** No therapy-specific regulation



“When patients cross European borders in search of CAM treatment, they may encounter substantial differences in the professional background of apparently identical CAM providers. They may also face a completely different reimbursement system, and if the treatment they undergo results in unwanted adverse or side effects they will be differently safeguarded depending on which state they are in. **Every aspect of the current situation can thus be a threat to patient safety.** In post-modern Europe where patient choice in health care is seen as a core value, **this confusing European market makes any informed treatment-seeking very challenging**”.

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threat to patient safety. In post-modern Europe where patient choice in health care is seen as a core value, this confusing European market makes any informed treatment-seeking very challenging”.

Patient safety

Patient information



Chiropractic

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- 13 No therapy-specific regulation



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

Homeopathy - Who may practice

Country	Specific homeopathy treatment regulation	Medical Doctors (MDs)	Medical Doctors with CAM training	Conventional practitioners (CPs) PS3 ¹	Conventional health personnel with CAM training	CAM practitioner ²	Others may practise	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)



Regulated profession and EU registered (10)	Regulated profession Not EU registered (6)	Regulated treatment Not regulated profession (10)	No regulation (13)
Cyprus	Belgium	Albania	Bosnia & Herzegovina
Denmark	Bulgaria	Austria	Croatia
Finland	Germany	Czech Republic	Greece
Iceland	Hungary	Estonia	Ireland
Liechtenstein	Israel	France	Latvia
Malta	Italy	Portugal	Lithuania
Norway		Romania	Luxembourg
Sweden		Serbia	Macedonia
Switzerland		Slovakia	Montenegro
UK		Slovenia	Poland
			Spain
			The Netherlands
			Turkey

Chiropractor is a **regulated profession** in **16 of the 39** countries.

10 countries have also registered chiropractor in **the EU regulated professions database**.

Educational and professional regulations differ in these countries, but in most of the 16 countries a chiropractor is recognized as a **conventional health profession**.

10 countries have some regulations on **chiropractic treatment**, but not a regulated profession called chiropractor.

13 countries have **no specific regulation** of chiropractic. However, the treatment may be regulated through CAM general legislation or conventional health legislation.

In some countries chiropractic treatment is regulated as **manual therapies**. In others we found regulations describing that other professionals may treat chiropractic, for example **physiotherapists**.



	Regulated profession and EU registered (10)
Cyprus	DSE-diploma (post-secondary education) including Annex II (ex 92/51, Annex C, D), Art. 11 c(4).
Denmark	PS3 – Diploma of post-secondary lever (3-4 years), Art. 11 d.
Finland	PS3 - Diploma of post-secondary level (3-4 years), Art. 11 d.
Iceland	PS3 - Diploma of post-secondary level (3-4 years), Art. 11 d.
Liechtenstein	PS3 - Diploma of post-secondary level (3-4 years), Art. 11 d.
Malta	PS3 - Diploma of post-secondary level (3-4 years), Art.11 d.
Norway	PS3- Diploma of post-secondary level (3-4 years), Art 11 d.
Sweden	PS3 - Diploma of post-secondary level (3-4 years), Art. 11 d.
Switzerland	PS3 - Diploma of post-secondary level (3-4 years), Art. 11 d.
UK	PS4- Diploma of post-secondary level (exactly 4 years)

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



Chiropractic

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	Regulated profession - Not EU registered (6)
Belgium	Colla law – Chamber of Chiropractic – not activated
Bulgaria	A master's degree in the professional area of medicine, dental medicine or pharmacology. A specialist's or bachelor's degree in the professional area of health care. A secondary education diploma and a certificate of completed training of at least four semesters at a higher medical school under terms and conditions set out by the Minister of Health and the Minister of Education and Science.
Germany	Regulated by law within the medical association
Hungary	Registered treatment and profession only for MDs with an exam from a medical university
Israel	Chiropractic Status Recognition Certificate from the Ministry of Health,
Italy	Acknowledged chiropractic treatment as a responsibility of a medical doctor, a dentist or primary health professionals with internationally approved chiropractic education



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Regulated treatment Not reg. profession (10)	Chiropractic treatment regulations
Albania	A therapeutic system
Austria	Specialise physicians in chiropractic manipulation.
Czech Republic	Public health care, may only be performed as a part of treatment in health facilities by health care professionals like doctors or physiotherapists
Estonia	Estonian Chiropractic Physicians have full medical diagnostic skills and are trained to provide physiotherapeutic modalities as well as prescriptive therapeutics and rehabilitative exercises
France	allows medical doctors, midwives, physiotherapists, nurse practitioners and other practitioners to practise chiropractic (diagnosis only by medical doctor)
Portugal	regulated by the Portuguese Law No 45/2003 on the provision of non-conventional therapies
Romania	CAM therapy in the group “ manual therapies ” in the law on CAM 118/2007
Serbia	CAM bylaw lists chiropractic as a method of treatment suitable for practise
Slovakia	is legal pursuant to general law- classification “ any other medical worker ”
Slovenia	“other CAM systems”, a method within “ manipulative and body-based methods ” A diploma from a medical faculty, knowledge of chiropractic and a valid licence



No regulation (13)	Members of European chiropractors' Union (EU)
Bosnia & Herzegovina	A draft of bylaw currently under preparation
Croatia	See the law of national classification of services
Greece	Hellenic Chiropractors' Association
Ireland	Chiropractic Association of Ireland
Latvia	Only MD's may provide diagnostic methods and treatment
Lithuania	Manual therapy are listed as medical specialties only to be practised by MD's
Luxembourg	Chiroletzebuerg . Treatment restricted to regulated health personnel.
Macedonia	Activities related to CAM– only if permission from MoH
Montenegro	National CAM regulations in progress
Poland	Polish Chiropractic Association . Only MD's may treat patients.
Spain	Asociación Española de Quiropráctica . CAM in general not regulated.
The Netherlands	Nederlandse Chiropractoren Associatie . Chiropractic is CAM.
Turkey	Turkish Chiropractic Association . MD's with additional qualification

Runciman et al. defines **patient safety** as *“the reduction of risk of unnecessary harm associated with healthcare to an acceptable minimum”*

Risk governance giving preference to patient safety **includes regulation as an important management tool.**

Regulations of importance for patient safety can cover **requirements on**

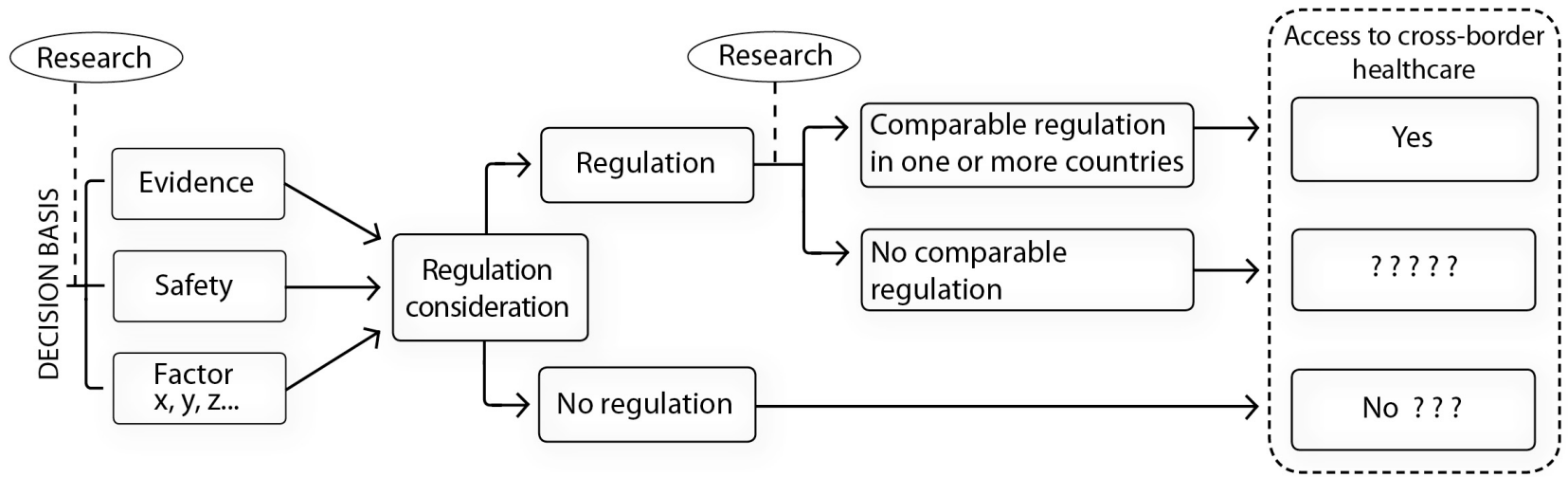
- Provider education and training
- Provision of standardized and safe treatments
- Mandatory or voluntary professionals’ registers
- Supervision – (given authority through legislation)
- Professional title protection

Patients’ rights can cover:

- Correct information
- Safe treatment and provider choice
- Right to submit treatment claims
- Reimbursement of treatment costs



Relationship between research, national regulation and cross-border Healthcare accessibility.



Conclusion

- CAM in Europe is **not regulated in accordance with current theory** dealing with
 - **risk governance,**
 - **risk regulation**
 - **patient safety.**
- European CAM regulation is **diverse and unclear.**
- Consequently, the **disharmonious landscape of CAM regulation in itself may impact patient safety.**



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.
- An **EU Directive on CAM** could be developed (like Cross-border Healthcare and regulation of health care professionals).
- 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.**



Thank
you!



Geneva, Red Cross museum