



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

Legal status and regulation of CAM in Europe

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ICCMR2013, WS26

The Pan-European research network for Complementary and Alternative
Medicine [CAMbrella]



London, April 13, 2013

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CAM

Legal Status and Regulations

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Place

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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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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



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Norwe

1. Every
receive
health
2. Near
acupur
over th

system



Homeopathy

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



Legislation and regulation of CAM

- Legal connection to **EUEFTA/EEA and Council of Europe**
- **CAM general** legislation
- Specific CAM **treatment** regulation
- **EU title** (Directive 2005/36/EC)
- **Regulated profession/ protected title**
- **Statutory/voluntary registers**

Who may practise:

- **Medical Doctors (MDs)**
- Medical Doctors with CAM training
- **Regulated health personnel**
- Regulated health personnel with CAM training
- **Other CAM practitioners**
- **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)

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
4. Directive *2001/83/EC (amending 2004/24/EC and 2004/27/EC)* on the Community code relating to medicinal products for human use



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



Patient safety

Risk governance 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



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

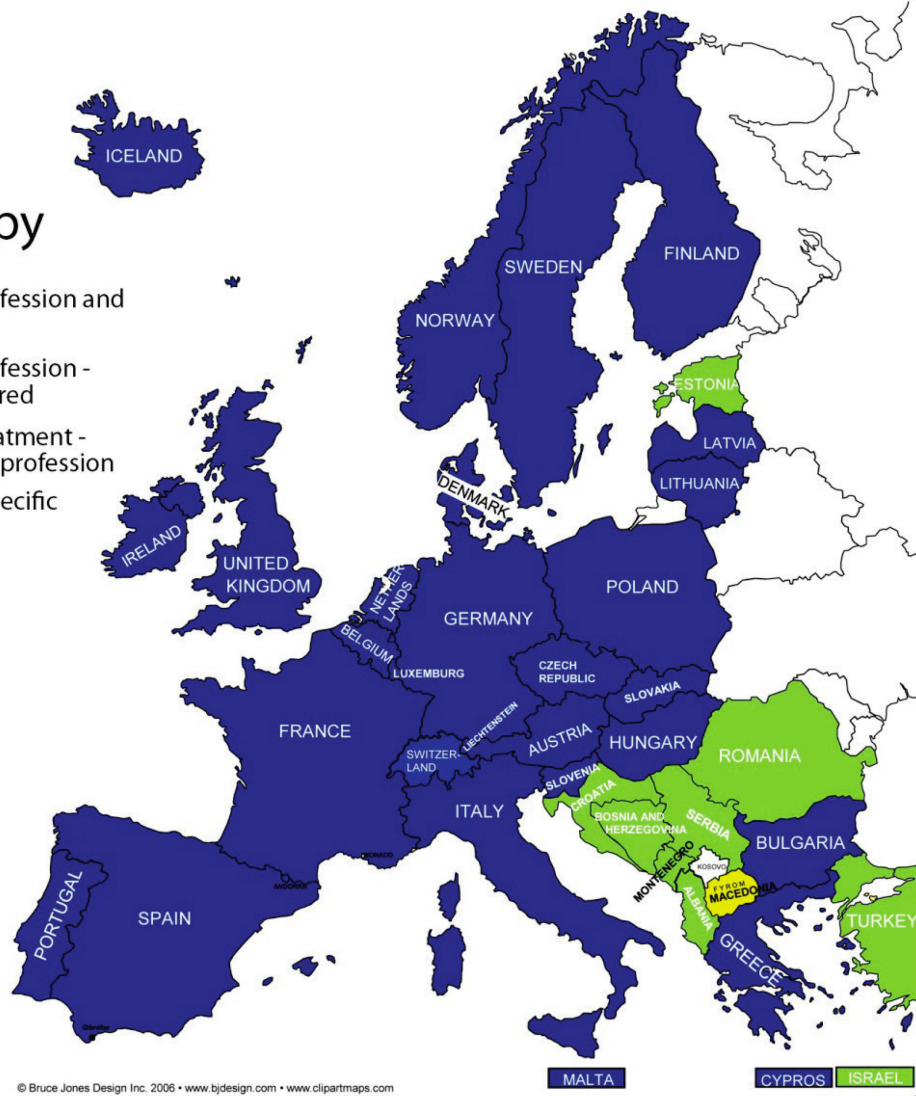
1. Legislation and regulation at the EU/EEA level
2. Voluntary harmonization.

**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**”.

“When patients cross European borders in search of CAM treatment, they may encounter substantial differences in the professional background of apparently identical CAM

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Patient safety

Patient information

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.
- 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.**



CAMbrella WP2 reports

All 3 reports are publicly available at:

www.nafkam.no

or

Die Universität Wien - Phaidra.

Please use the following links:

<http://phaidra.univie.ac.at/o:291583>

<http://phaidra.univie.ac.at/o:291682>

<http://phaidra.univie.ac.at/o:291585>

Thank
you!



Geneva, Red Cross museum



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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



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	
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	Treatment restricted to regulated health personnel.
Macedonia	Activities related to CAM– only if permission from MoH
Montenegro	National CAM regulations in progress
Poland	Only MD's may treat patients.
Spain	CAM in general not regulated.
The Netherlands	Chiropractic is CAM.
Turkey	MD's with additional qualification



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