



«CAMCrossEurope» regulation Impact on patient safety – with focus on supervision

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Scientific background

- **CAMbrella**- A pan-European research network for Complementary and Alternative Medicine (CAM) (*FP7-HEALTH-2009, GA No. 241951*).

Deliverable 9 - WP 2 - Legal status and regulation of CAM in Europe (December 2012).



cambrella

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

- **Master thesis, Solveig Wiesener:**

Disharmonized regulation of Complementary and Alternative Medicine (CAM) in Europe – Implications for patient safety (January 2013).





CAMCrossEurope

Patient safety
Patient information

CAM Regulation – objectives

The objective of giving an overview of the regulation of Complementary and Alternative Medicine (CAM) is primarily

- ❖ **to enable European citizens to make informed and safe choices when they seek CAM treatments.**
- ❖ European citizens are seeking CAM, also when **offered outside their national health care system.**
- ❖ **Regulation** is an important **management tool in risk governance** of health care services.

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.

(Lisbon Treaty; in TITLE XIV Public Health Article 168 number 7)

- This will, of course, **also apply to traditional, complementary, alternative and integrative medicine.**

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.

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**

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.

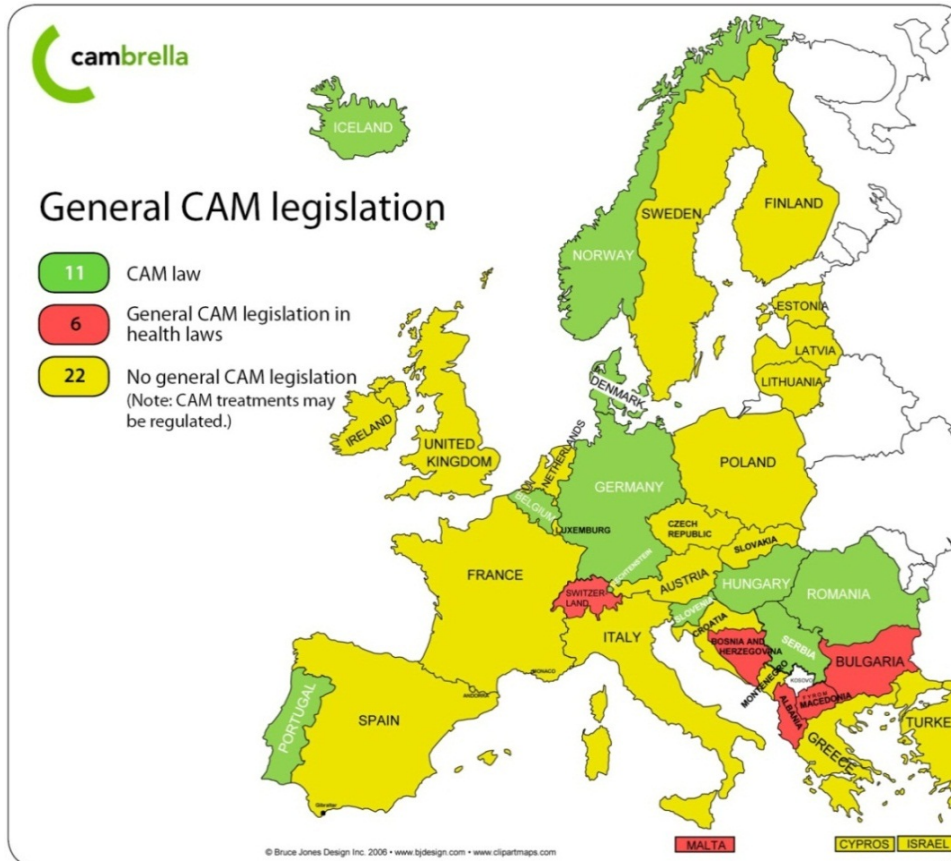
Legislation and regulation of CAM

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

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**

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.

Treatments included in the CAMbrella CAM regulation study

1. *Acupuncture*
2. *Anthroposophic medicine*
3. *Ayurveda*
4. *Chiropractic*
5. *Herbal medicine/Phytotherapy*
6. *Homeopathy*
7. *Massage*
8. *Naprapathy*
9. *Naturopathy*
10. *Neural therapy*
11. *Osteopathy*
12. *Traditional Chinese Medicine (TCM)*
13. *Others- of special interest for each country*
14. *Physiotherapy – for comparison*



Acupuncture

- 2 Regulated profession and EU registered
- 0 Regulated profession - not EU registered
- 24 Regulated treatment - not regulated profession
- 13 No therapy-specific regulation



Portugal:
New
profession

Turkey:
New
law

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Homeopathy

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



Belgium:
New
Only
doctors

Portugal:
New
profession

Turkey:
New law

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 and Council of Europe

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 (*amended by 2004/24/EC and 2004/27/EC*) on the Community code relating to medicinal products for human use.



Chiropractic

- 10** Regulated profession and EU registered
- 6** Regulated profession - not EU registered
- 10** Regulated treatment - not regulated profession
- 13** No therapy-specific regulation



Belgium :
New profession

France:
New: EU-registered profession

Portugal:
New profession

Turkey:
New regulation – provide only by medical profession



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). NEW: March 24, 2014 training chiropractors
Portugal	regulated by the Portuguese Law No 45/2003 on the provision of non-conventional therapies . NEW: Amendment Sept 2013-training, protected title
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



Osteopathy

- 6 Regulated profession and EU registered
- 3 Regulated profession - not EU registered
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Belgium:
New regulation

France:
New: Eu-registered

Portugal:
New profession

Turkey:
New regulation – provide only by medical profession



Regulated profession and EU registered (6)	Osteopathy treatment regulations
Finland FORE	Finland require a qualification level PS3 – diploma of post-secondary level (3-4 years)
Iceland FORE	Iceland require a qualification level PS3 – diploma of post-secondary level (3-4 years)
Liechtenstein	Liechtenstein require a qualification level PS3 – diploma of post-secondary level (3-4 years)
Malta FORE	Malta require a qualification level PS3 – diploma of post-secondary level (3-4 years)
Switzerland Eur Ost DO	In Switzerland the qualification level is 5 years plus 2 years of internship
UK FORE Eur Ost DO	In UK “osteopath” is registered with a qualification level PS4-diploma of post-secondary level (exactly 4 years).

Consequences for European patients

- For similarly labeled treatments; an **unpredictable level of professional competence** and treatment standards.
- **Different systems of authority regulation** of quality of services provided.
- Unpredictable system of **reimbursement** for services provided.
- **Inadequate safeguard systems** if the treatment they undergo results in unwanted adverse or side effects.
- Limited and complex opportunities for **complaints**.

Every aspect of the current situation can be a threat to patient safety

Consequences for European CAM practitioners

- Serious concerns with regard to the **predictability, quality and safety of health care** delivery to European citizens.
- The establishment of **collegial common ground** is very challenging.
- Substantial differences in the **professional background** of apparently identical CAM providers.

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

Patient safety

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





Supervision of CAM

- ❖ CAMbrella- overview of 39 European countries
- ❖ EPSO – European Partnership for Supervisory Organisations in Health Services and Social Care
- ❖ Risk Governance with risk understanding and indicators.
- ❖ 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
 - ❖ **Collaboration on implementation**



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13

No regulation

Supervision?

Bosnia and Herzegovina	Yes - Law on health care No - Law not passed yet in federation
Croatia	No
Greece	No
Ireland	No or Yes, if regulated medical personnel
Latvia	No
Lithuania	No/Yes - Not allowed for non-medical professionals
Luxembourg	No Not recognized profession
Macedonia	No or Yes, if permission to practice - included in the public health law
Montenegro	No
Netherlands	No - Not included in the individual health care professions act
Poland	No
Spain	No
Turkey	Yes- provide by medical doctor or supervised by a medical doctor

NEW!

The European Committee for standardization (CEN)

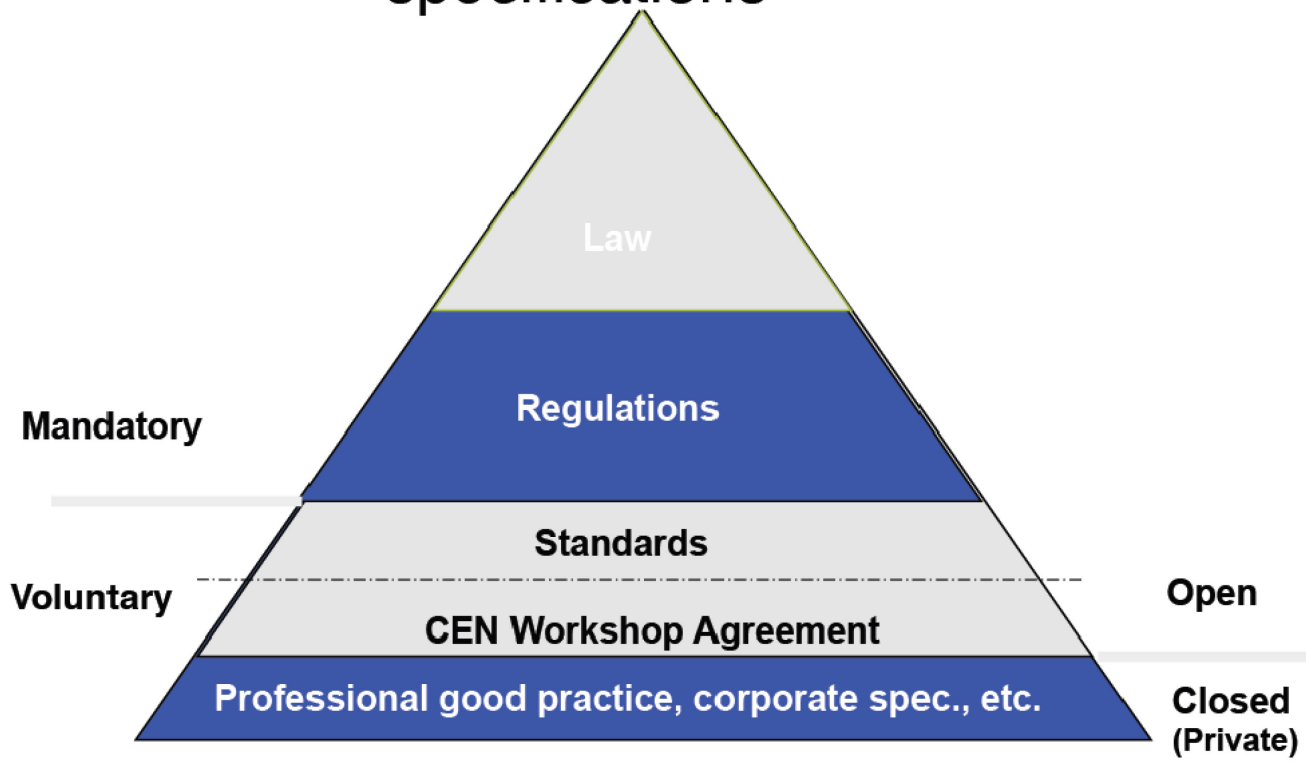


- European standardization body for the development of standards in all areas

- CAM technical committees—
 - ❖ Homeopathy for medical doctors
 - ❖ Osteopathy
 - ❖ Chiropractic



Standards, regulations and private specifications



Ref: Dr.Thomas Peinbauer, ECH President



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24

No regulation

CEN
TC 414

Albania	
Austria	
Bosnia and Herzegovina	
Croatia	
Cyprus	
Czech Republic	
Denmark	
Estonia	
Germany	
Greece	
Ireland	
Israel	
Lithuania	
Luxembourg	
Macedonia	
Montenegro	
Netherland	
Norway	
Poland	
Serbia	
Slovakia	
Spain	
Sweden	
Turkey NEW!	



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15	CEN TC 427
No regulation	
Bosnia and Herzegovina	
Cyprus	
Finland	
Iceland	
Ireland	
Israel	
Luxembourg	
Macedonia	
Malta	
Montenegro	
Netherlands	
Norway	
Sweden	
Slovakia	
Turkey NEW!	



Chiropractic

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13	CEN TC 394
No regulation	
Bosnia and Herzegovina	
Croatia	
Greece	
Ireland	
Latvia	
Lithuania	
Luxembourg	
Macedonia	
Montenegro	
Netherlands	
Poland	
Spain	
Turkey NEW!	



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13

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Supervision?

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Netherlands	No - Not included in the individual health care professions act
Poland	No
Spain	No
Turkey	NEW! Yes - provide by medical doctor or supervised by a medical doctor

Questions to ask for health authorities

- To supervise CAM providers - which regulation is requested?
- A medical doctor provides CAM – Supervision!
- A medical doctor provides homeopathy private?
- A regulated chiropractor - Supervision!
- A physiotherapeut provides chiropractic - ?
- General CAM regulation- it is allowed to practise homeopathy!- what about the homeopath (non-medical provider) following a CEN standard??

Possible ways forward

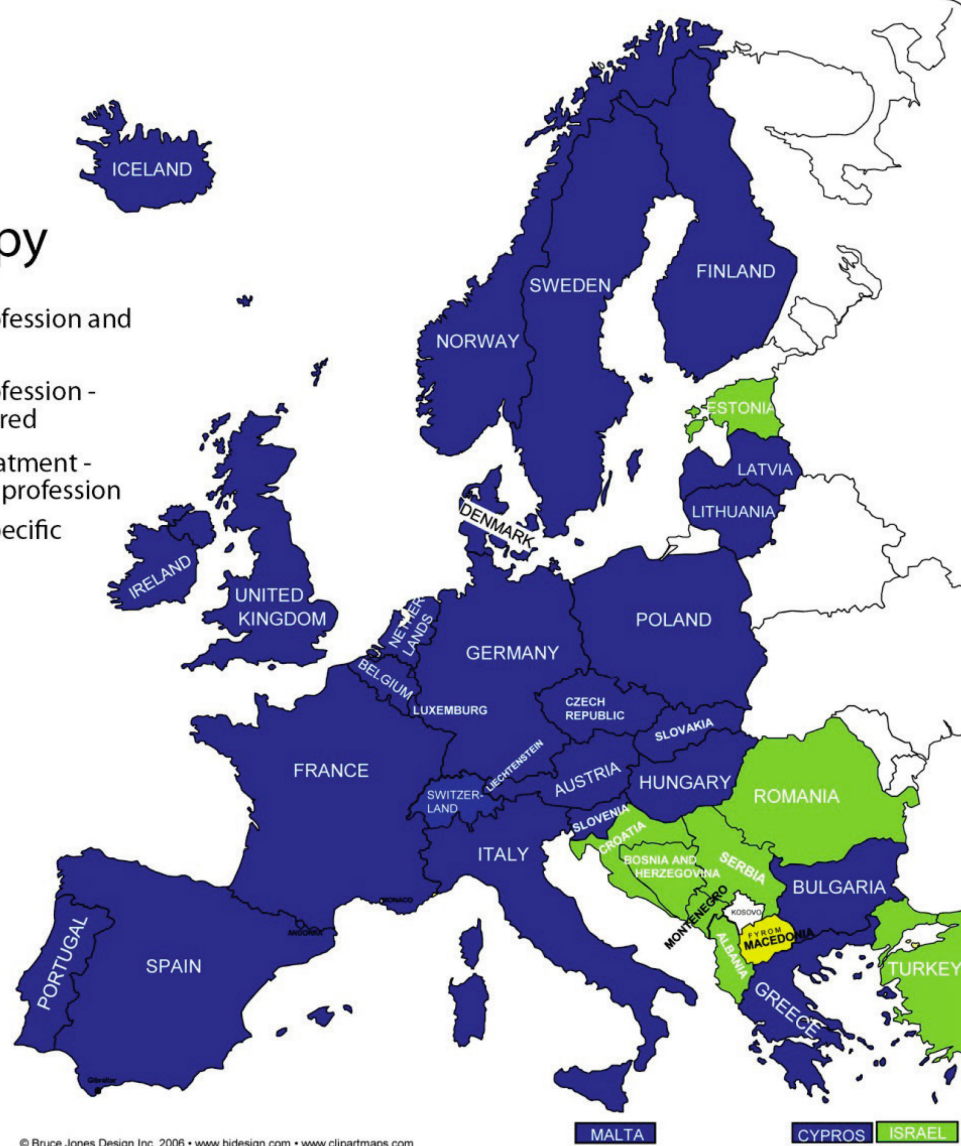
1. Legislation and regulation at the EU/EEA level
2. National/regional collaboration on regulation
3. Self-regulation (CEN)
4. Voluntary harmonization.

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



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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>



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

Master thesis:

<http://brage.bibsys.no/uis/retrieve/5713/Wiesener.Solveig.pdf>



References

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- 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; Available from
<http://phaidra.univie.ac.at/o:291583>
<http://phaidra.univie.ac.at/o:291682>
<http://phaidra.univie.ac.at/o:291585>

New website: <http://nafkam-camregulation.uit.no>

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CAM Regulation

Traditional, Complementary & Alternative Medicine:
Legal and regulatory status - Governmental supervision - Reimbursement status



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Home

Welcome to NAFKAM's website on the regulation of Traditional, Complementary and Alternative Medicine (CAM) in 39 European/EU countries.

This website contains hard copies of the findings in [work package \(WP\) 2](#) in the EU-funded CAMbrella project, which were delivered on December 31, 2012. New regulation that has come to our attention after 2012 is included as [News](#).

The database gives information from 39 countries regarding both CAM regulation in general as well as specific regulatory issues with regard to 12 selected CAM treatments on the following subjects:

- Legal and regulatory status
- Governmental supervision
- Reimbursement status

Objective

European citizens are seeking Complementary and Alternative Medicine, also when offered outside their national health care system. Regulation is an important management tool in risk governance of health care services. The objective of giving an overview of the regulation of Complementary and Alternative Medicine (CAM) in the European/EU countries is primarily to enable European citizens to make informed and safe choices when they seek CAM treatments. [Read more](#)

Filter options

Country

Therapy/Summary/News

Show results

Search

Norway's National Research Center in Complementary and Alternative Medicine (NAFKAM) is organized as a center at the Faculty of Medicine, at UiT The Arctic University of Norway.

nafkam
The National Research Center in
Complementary and Alternative Medicine



UiT / THE ARCTIC UNIVERSITY
OF NORWAY

Good luck with
your supervision!!

Takk!
Thank you!
Danke schön!



Geneva, Red Cross museum