



«CAMCrossEurope» regulation
Impact on patient safety
– with focus on India-Nor collaboration

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CAMCrossEurope

Patient safety
Patient information

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**

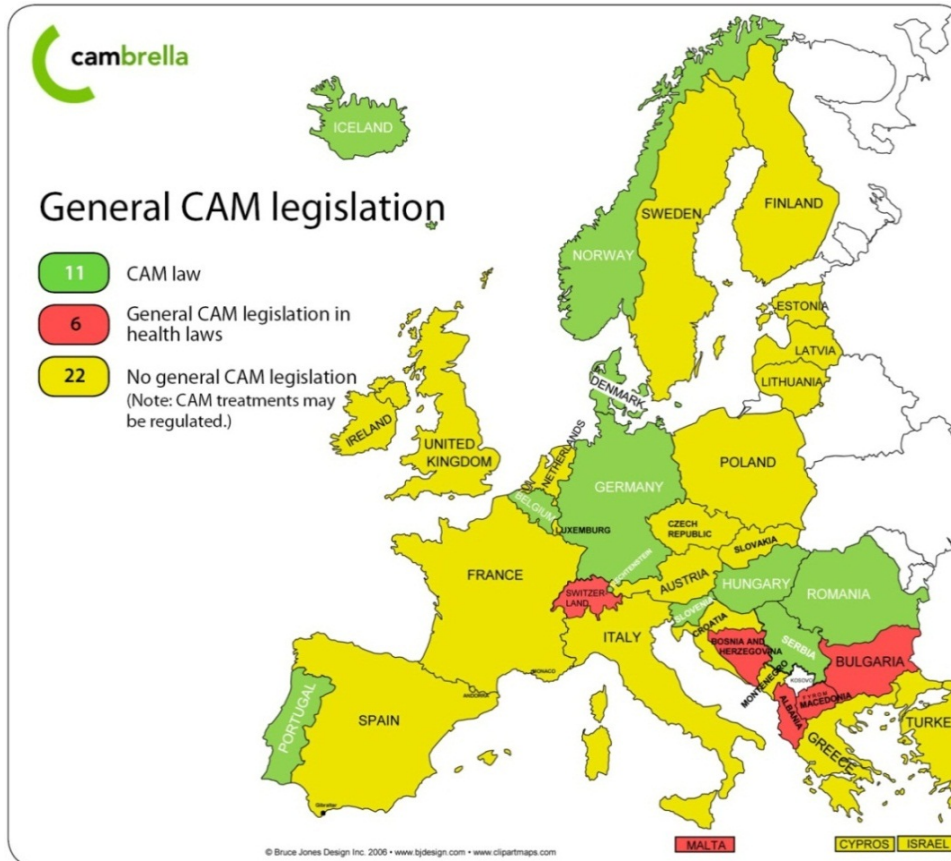
Legislation and regulation of CAM

- 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
- 25** Regulated treatment - not regulated profession
- 12** 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
- 22** Regulated treatment - not regulated profession
- 14** No therapy-specific regulation



Belgium
New:
Only
doctors

Portugal
New
profession

Turkey:
New
profession

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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-
medical
profession



Osteopathy

- 6 Regulated profession and EU registered
- 3 Regulated profession - not EU registered
- 6 Regulated treatment - not regulated profession
- 24 No therapy-specific regulation



Belgium:
New regulation

France:
New: Eu-registered

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Consequences for European patients

- For similarly labeled treatments; an unpredictable level of professional competence and treatment standards.
- For similarly labeled treatments; an unpredictable level of professional competence.
- 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.

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



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>



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](#)

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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

India – Nor application 2016 FOCUS and Discussions

- To describe regulation in India – model CAMbrella project??
- Describe differences between India and Europe
- Discuss pro and cons for the different systems of regulation

Discussions regulation

- What happens when government policy and patients goes towards modern medicine?
 - Do the western health professionals know TK/CAM practises?
 - Will the TK/CAM practitioners know the western medicine
- Education?
- Standardization of practices?
- Patient safety aspects?

Good luck with
your project
!!

Takk!
Thank you!
Danke schön!



Geneva, Red Cross museum