



«CAMCrossEurope» regulation – impact on patient safety

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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).



- **Master thesis, Solveig Wiesener:** Disharmonized regulation of Complementary and Alternative Medicine (CAM) in Europe – Implications for patient 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.

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

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

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.

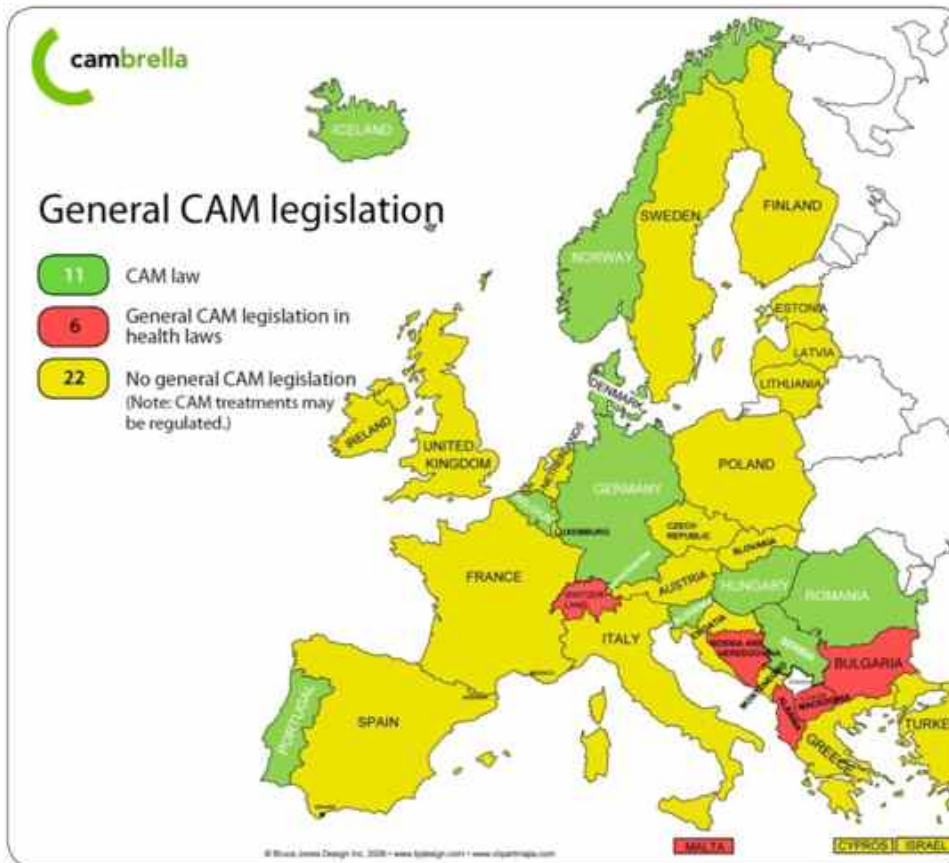
Legislation and regulation of CAM

- Legal connection to **EUEFTA/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**

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.



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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Homeopathy

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



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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



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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

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



Consequences for European patients

1. A wide diversity of available treatments and providers
2. For similarly labeled treatments; an unpredictable level of professional competence.
3. Different systems of authority regulation of quality of services provided.
4. Unpredictable system of reimbursement for services provided.
5. Limited and complex opportunities for complaints.

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

Consequences for European CAM practitioners

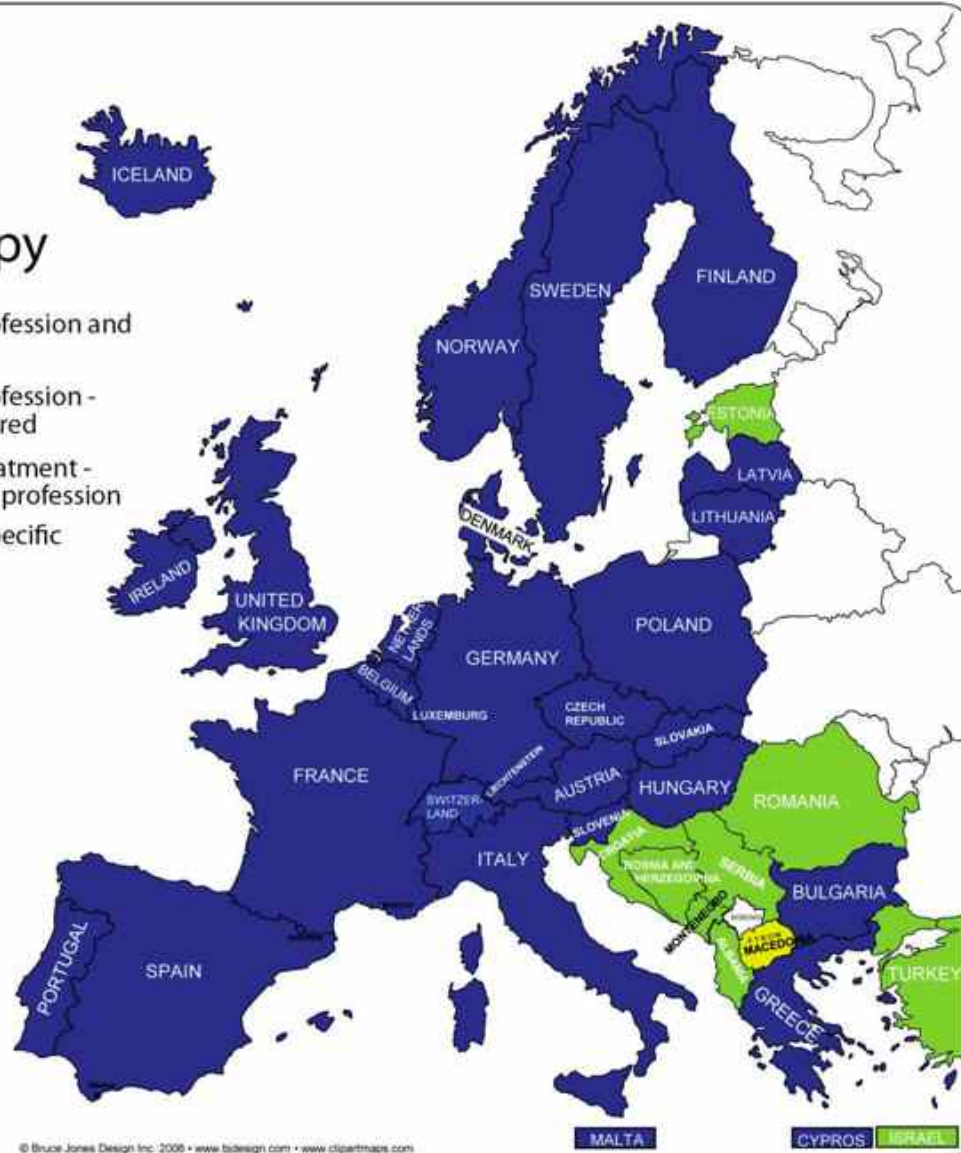
1. Serious concerns with regard to the predictability, quality and safety of health care delivery to European citizens.
2. The establishment of collegial common ground is very challenging.

The current situation can be a threat to patient safety



Physiotherapy

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



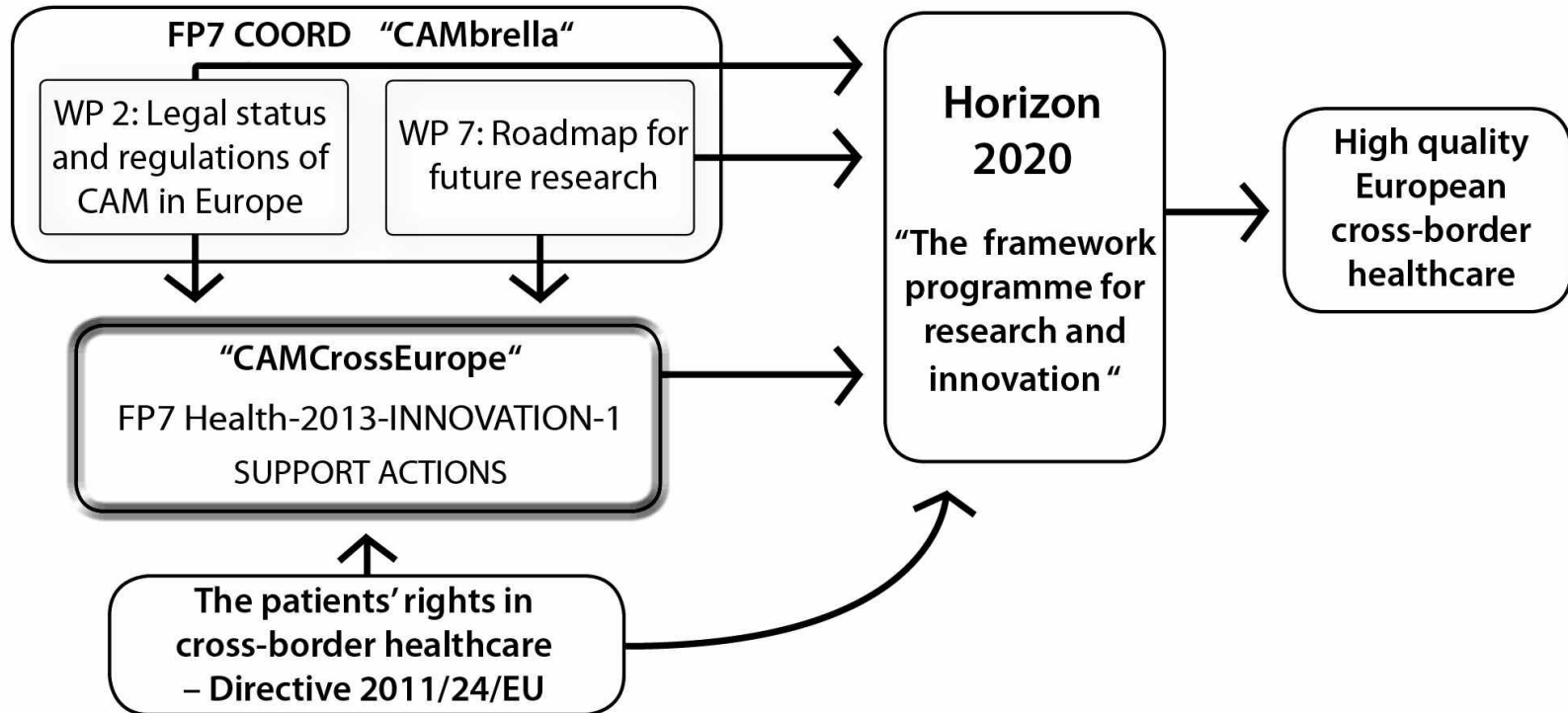
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“When patients cross European borders in search of CAM treatment, they may encounter substantial differences in the professional background of apparently identical CAM providers. They may also face a completely different reimbursement system, and if 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**”.

CAMCrossEurope

Figure 2 Interconnections between FP7 “CAMbrella”, FP7 “CAMCrossEurope”, Directive 2011/24/EU and Horizon 2020



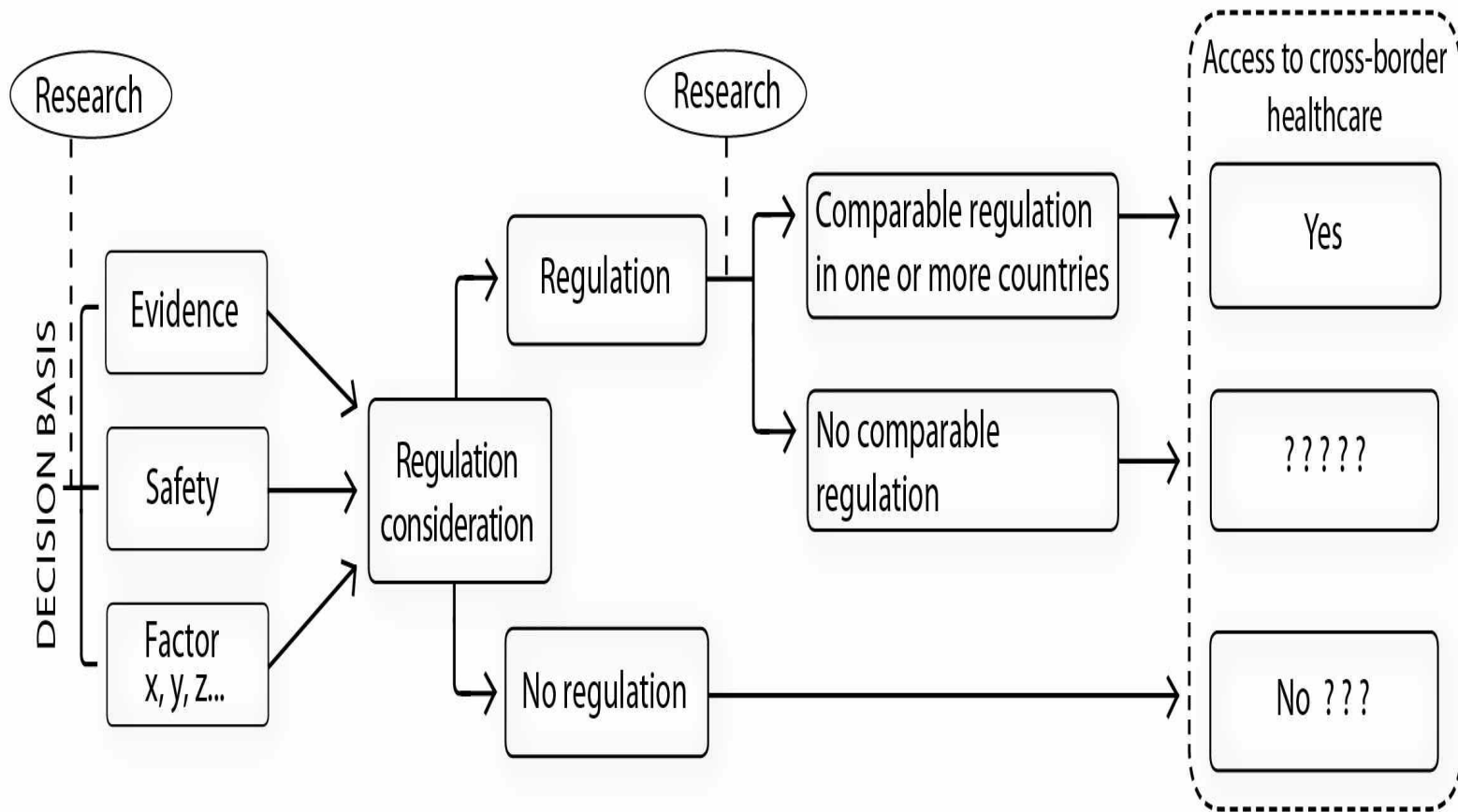


Figure 1 Relationship between research, national regulation and cross-border healthcare accessibility

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>



cambrella

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

Master thesis:

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



Thank
you!



Geneva,
Red Cross museum