



«CAMCrossEurope» regulation – with an osteopathy focus Will harmonization improve patient safety?

Solveig Wiesener
Senior Adviser
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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).



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 **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**

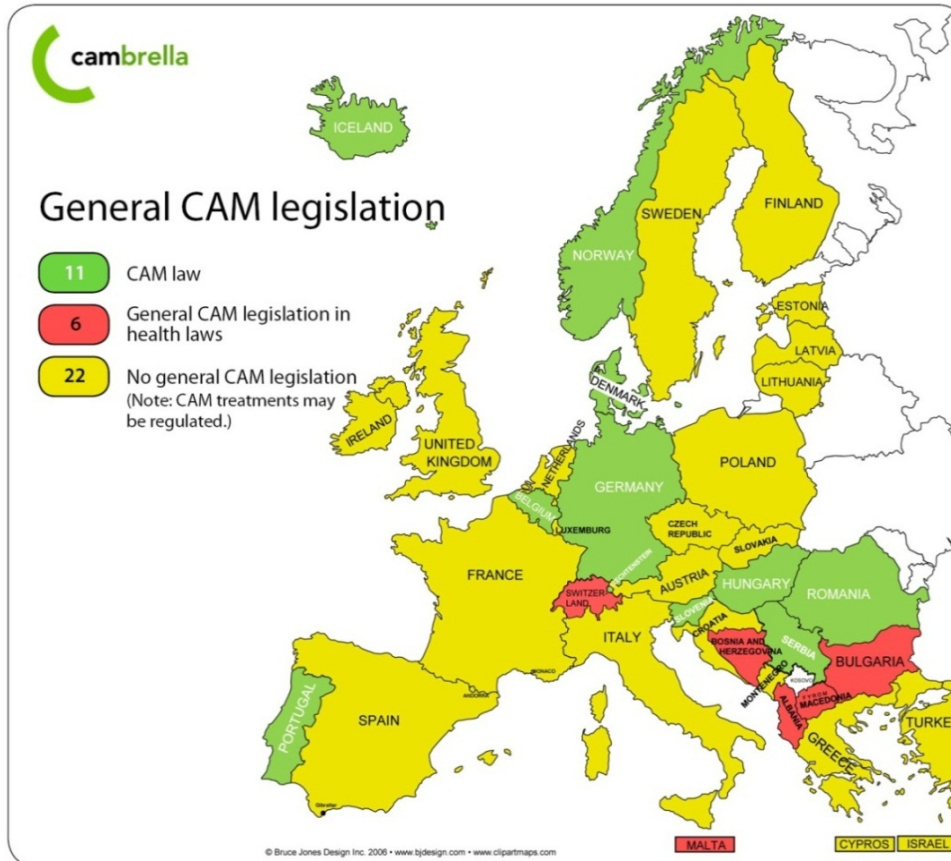
Who may practise:

- **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**

Legal changes after CAMbrella delivery (November 2012)

- **Portugal:** New Law 2 September 2013
Acupuncture; Phytotherapy; Homeopathy;
Traditional Chinese Medicine; Naturopathy;
Osteopathy; Chiropractic
- **Belgium**
The Colla Law- accepted ???
- **Italy**
22 March 2013 – osteopath profession law –
submitted proposal to the Senate

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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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



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Osteopathy

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



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Osteopathy regulations - countries

Regulated profession and EU registered (6)	Regulated profession Not EU registered (3)	Regulated treatment Not regulated profession (6)	No regulation (24)
Finland	France	Belgium	
Iceland	Hungary	Bulgaria	
Liechtenstein	Latvia	Italy	
Malta		Portugal	
Switzerland		Romania	
UK		Slovenia	

Regulated profession and EU registered (6)	Regulated profession Not EU registered 3)	Regulated treatment Not regulated profession (6)	No regulation (24)
Finland FORE	France FORE Eur Ost DO	Belgium FORE Eur Ost DO	Albania
Iceland FORE	Hungary	Bulgaria	Austria FORE Eur Ost DO
Liechtenstein	Latvia	Italy FORE Eur Ost DO	Bosnia and Herzegovina
Malta FORE	<i>(NEW Portugal 2013)</i>	Portugal FORE Eur Ost DO ★	Croatia
Switzerland Eur Ost DO		Romania Eur Ost DO	Cyprus Eur Ost DO
UK FORE Eur Ost DO		Slovenia	The Czech Republic
			Denmark FORE
			Estonia
			Germany FORE Eur Ost DO
			Greece Eur Ost DO
			Ireland FORE
			Israel FORE
			Lithuania
			Luxembourg Eur Ost DO
			Macedonia
			Montenegro
			Norway FORE
			Poland Eur Ost DO
			Serbia
			Slovakia
			Spain FORE Eur Ost DO
			Sweden FORE Eur Ost DO
			The Netherlands FORE Eur Ost DO
			Turkey



Regulated treatment Not reg. profession (6)	Osteopathy treatment regulations
Belgium FORE EUR Ost Do	The act on non-conventional practices (the “Law of minister Colla”) was adopted by the Belgian Parliament in 1999. The CAM law includes a “ Chamber of osteopathy ”. Since the Colla law is not fully in effect, the practice of a CAM by a non-doctor is still illegal.
Bulgaria	The health law includes “ non-conventional physical methods ” which may include osteopathy.
Italy FORE EUR Ost Do	Court rulings have acknowledged osteopathic treatment as a responsibility of a medical doctor, a dentist or regulated health professionals with internationally approved education in osteopathy. 22 March 2013 osteopath profession law - submitted proposal to the Senate.
Portugal FORE EUR Ost Do	<i>New law Sept 2013– Regulated profession, not registered in the EU professionals ‘ database.</i> Since 2003 Osteopathy treatment has been regulated by the Portuguese Law No 45/2003 of 22 august 2003 on the provision of non-conventional therapies .
Romania EUR Ost Do	Osteopathy is legally recognized as a CAM therapy in the group “ manual therapies ” in the law on CAM 118/2007. Only medical doctors, dentists and pharmacists with approved additional qualification are allowed to practise osteopathy.
Slovenia	Osteopathy is listed within “ other CAM systems ”, a method defined within “ manipulative and body-based methods ”(§4). Osteopathy shall only be practised by those who have a diploma from a medical faculty, knowledge of osteopathy and a valid licence.



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).



Regulated profession Not EU registered (3)	Osteopathy treatment regulations
France FORE Eur Ost DO	In France legislation provides a medical qualification to practise osteopathy . A new law on chiropractic and osteopathy is in progress
Hungary	In Hungary only doctors may practise and osteopathy is regulated as “ manual therapy ”.
Latvia	In Latvia doctors may have a doctoral degree of osteopathy and a rank as “ doctor of osteopathy ”.

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

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

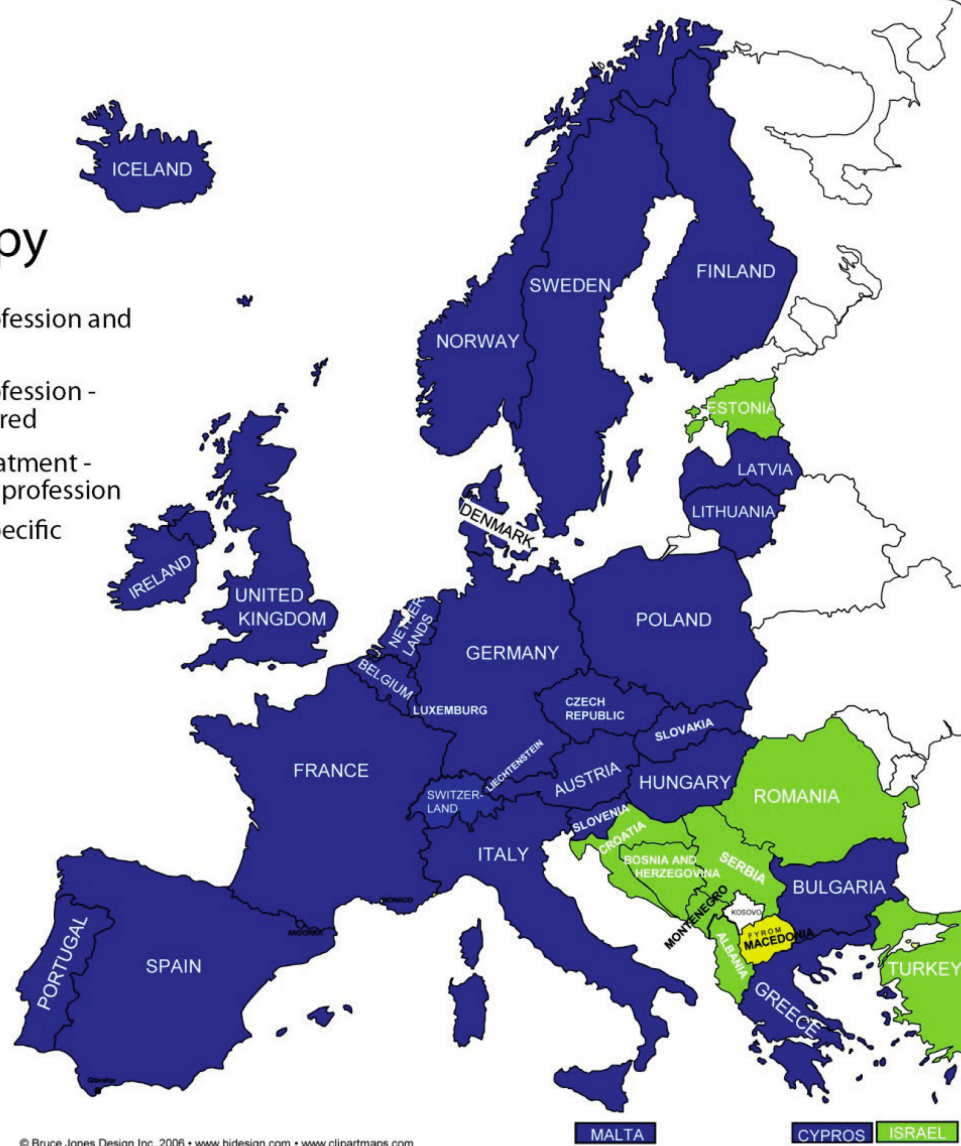
1. Legislation and regulation at the EU/EEA level
2. Voluntary harmonization.

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



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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

Patient safety
Patient information

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

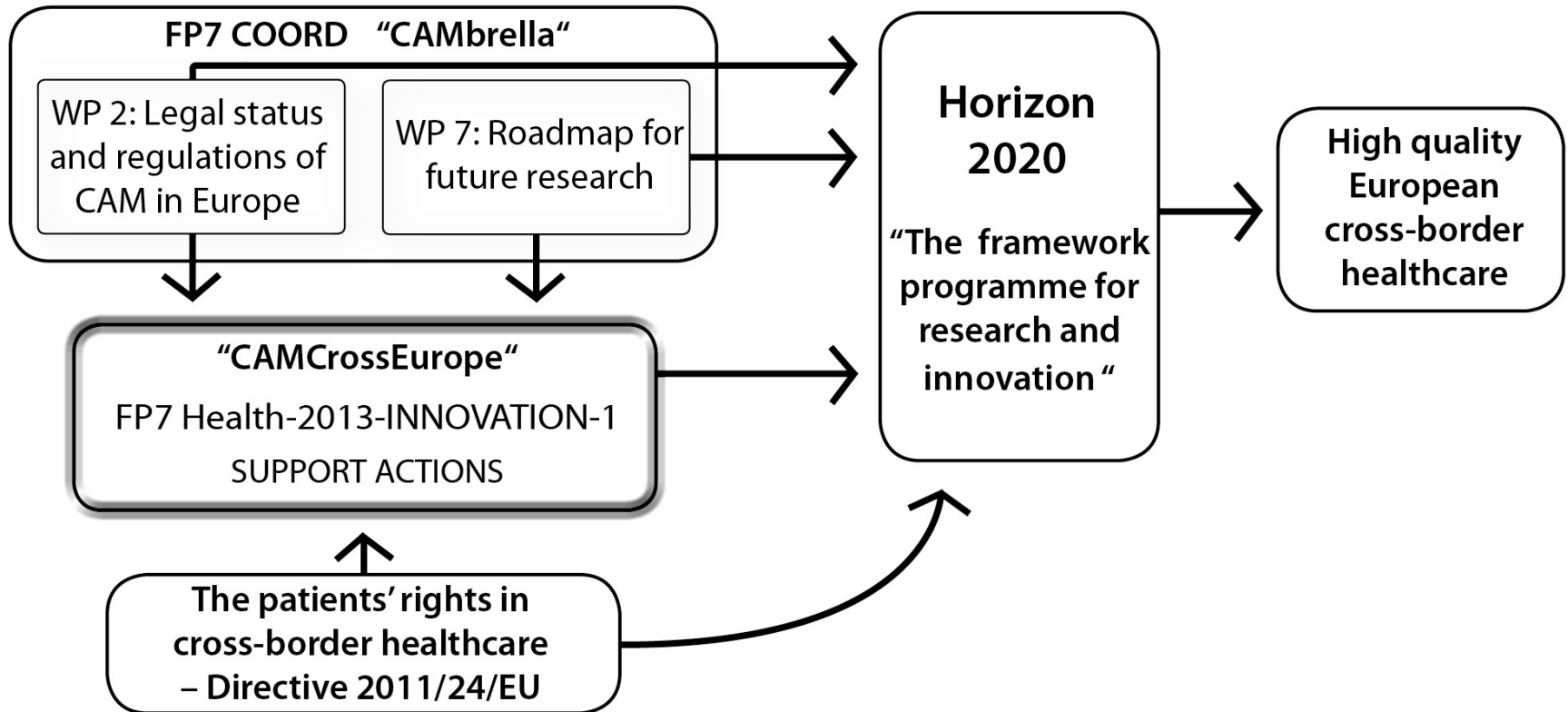
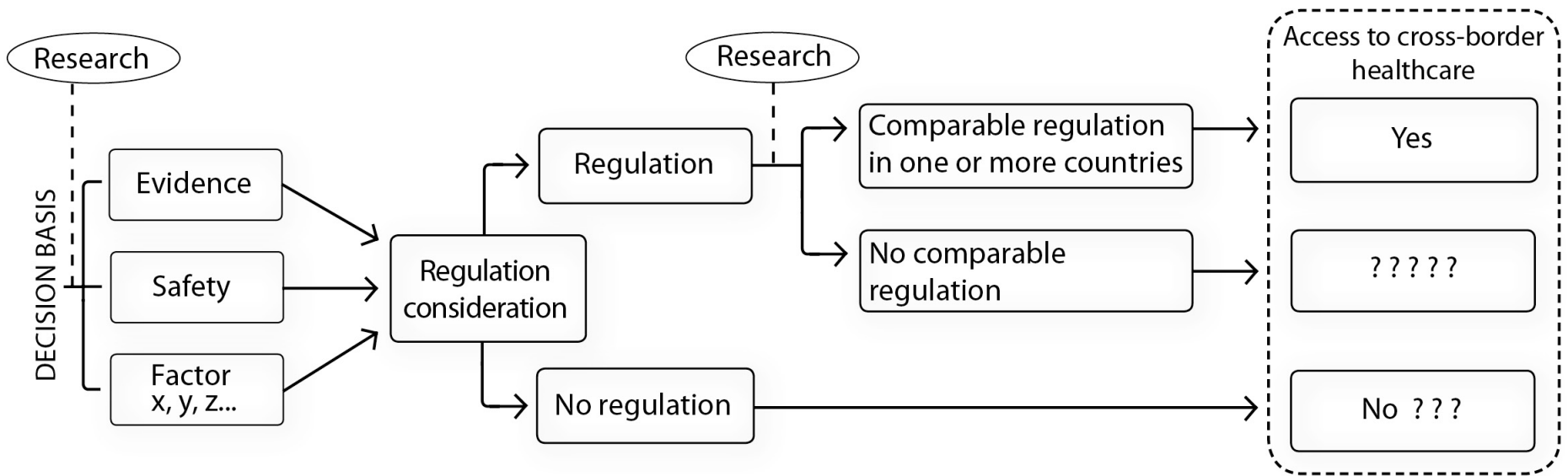


Figure 1 Relationship between research, national regulation and cross-border healthcare accessibility



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**.



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

- **EPSO – European Partnership for Supervisory Organisations in Health and Social Care**
- Risk Management and Risk Indicators – New working group
- **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

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>



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<http://phaidra.univie.ac.at/o:291682>
<http://phaidra.univie.ac.at/o:291585>

Takk!
Thank you!
Danke schön!



Geneva, Red Cross museum