



# Legal Status and Regulations

## Presentation

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## Place

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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

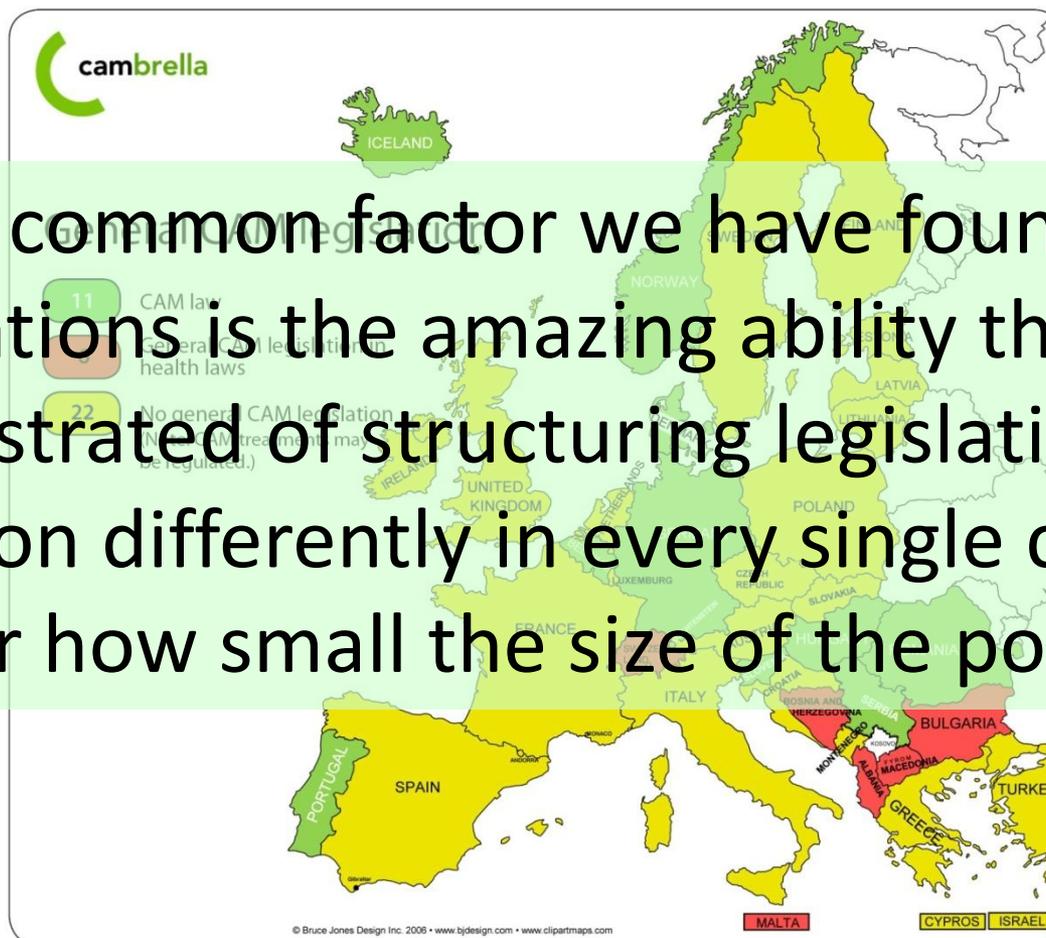
# CAMbrella WP2 Methodology

**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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# 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.

# TCM herbal medicinal products

1. Must comply with EU directives
2. Can be registered or given marketing authorization through
  - Standard procedure (Full application)
  - Well-established use procedure
  - Simplified registration procedure for traditional-use registration



# Homeopathy

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



# Homeopathy in Sweden

1. “Anyone” not authorized as health personnel can practice homeopathy
2. Health personnel are obliged to “carry out their work in accordance with science and proven experience”
3. BUT, Patient safety issues “trump” this obligation according to the Swedish Supreme Administrative Court



# Chiropractic

- 10 Regulated profession and EU registered
- 6 Regulated profession - not EU registered
- 11 Regulated treatment - not regulated profession
- 12 No therapy-specific regulation



# Consequences for European patients

1. A wide diversity of available treatments and providers
  2. For similar level of care
  3. Different quality of services
  4. Unpredictable provider quality
  5. Limited patient choice
- 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

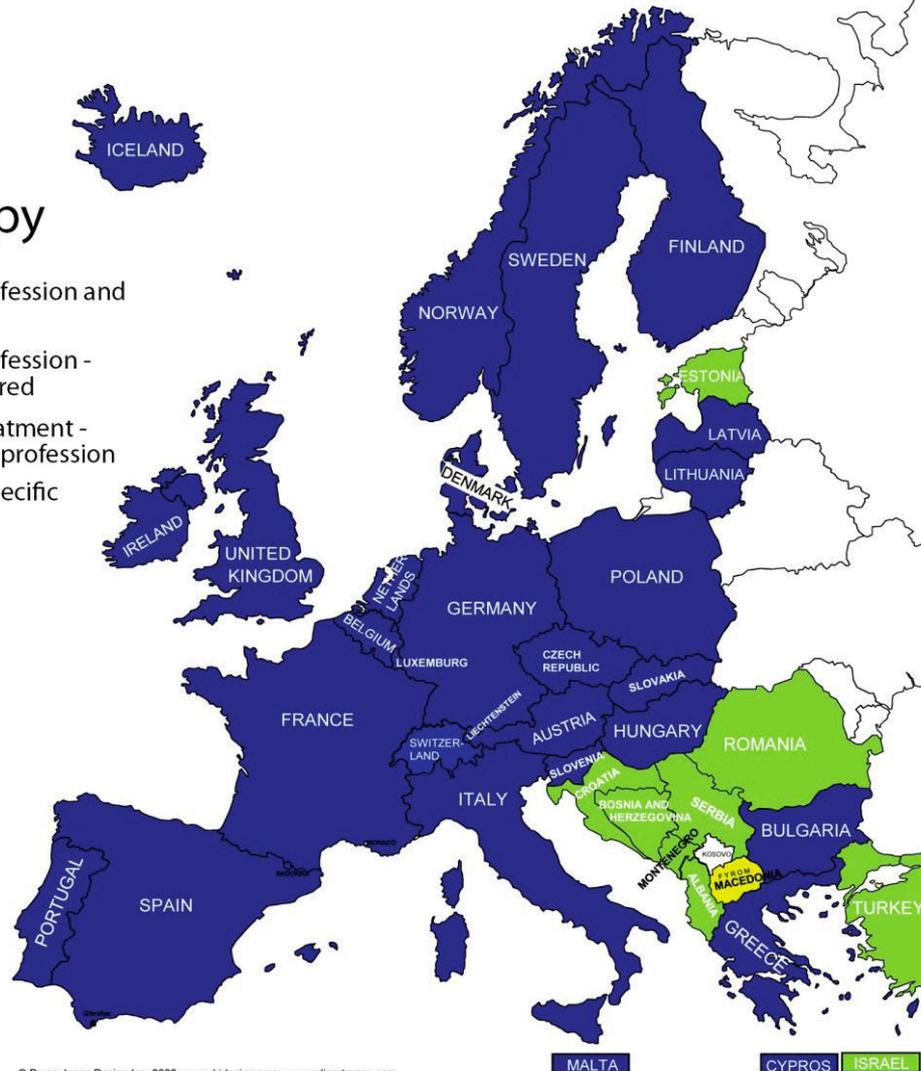
1. Legislation and regulation at the EU/EEA level
2. Voluntary harmonization.

**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

Patient safety

Online tomorrow

morning at

[www.nafkam.no](http://www.nafkam.no)

treatment-seeking very challenging”.