nafkam

The National Research Center in
Complementary and Alternative Medicine

«CAMCrossEurope» regulation Impact on patient safety

– with focus on India-Nor collaboration

Solveig Wiesener

Senior Adviser, MSc Risk management and societal safety

Indi-Nor project meeting

Bangalore

07-15. September 2015

UiT / THE ARCTIC UNIVERSITY OF NORWAY

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**

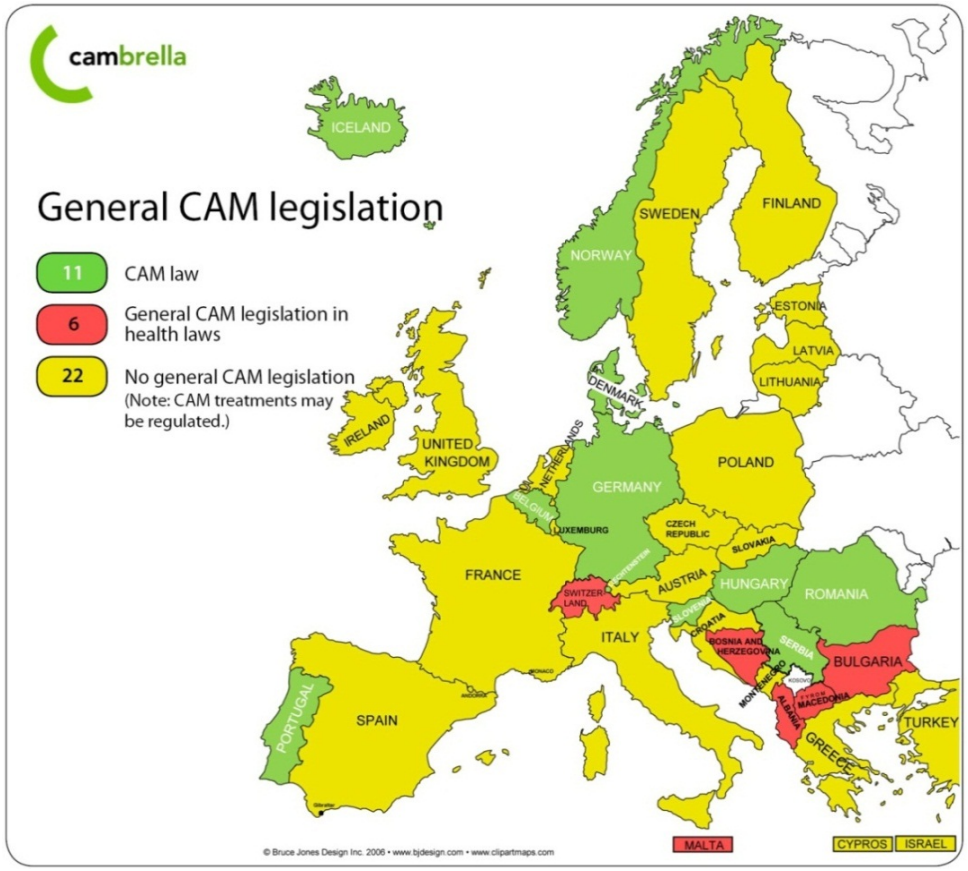
Legislation and regulation of CAM

- 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**

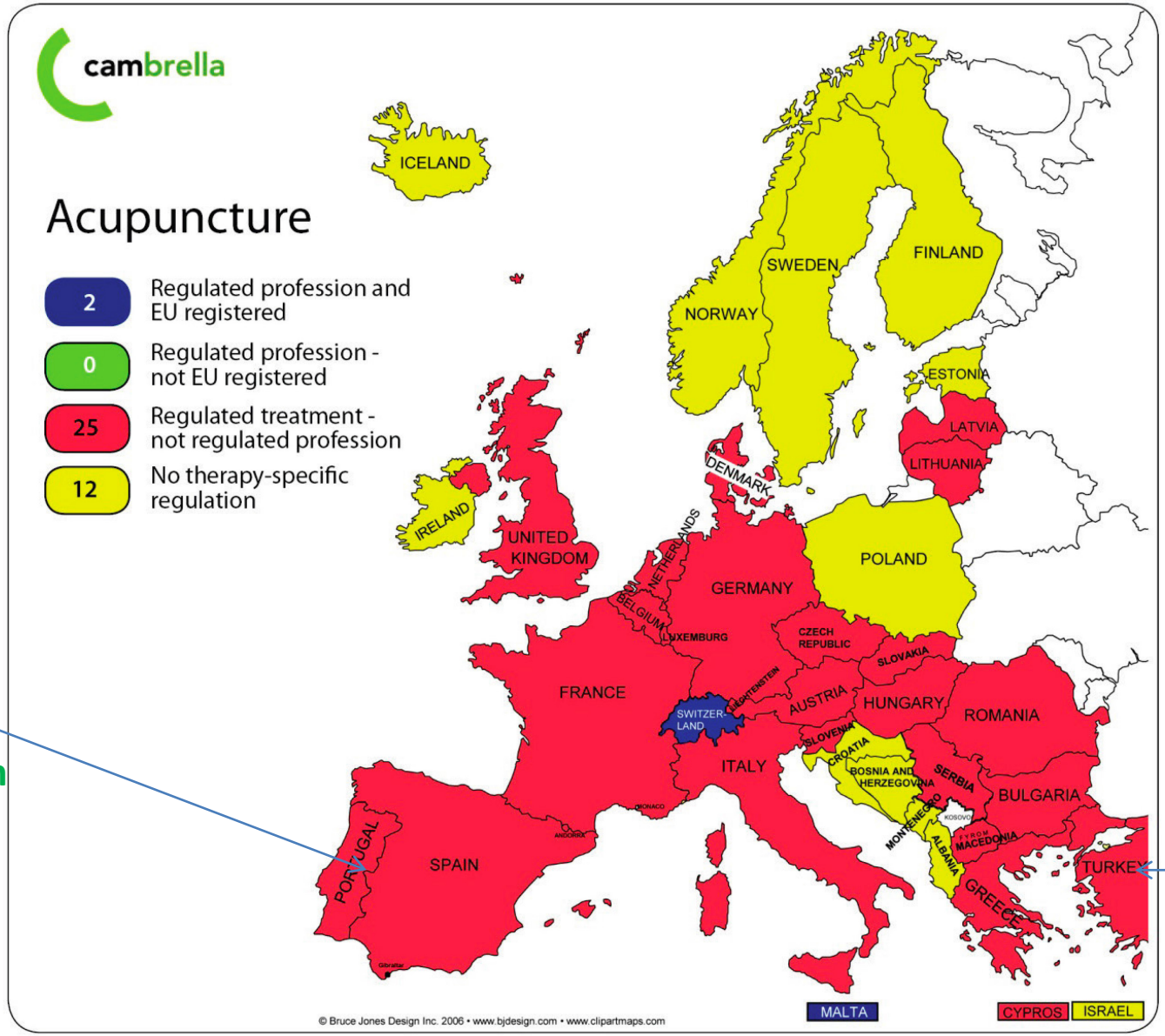
European CAM legislation



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*



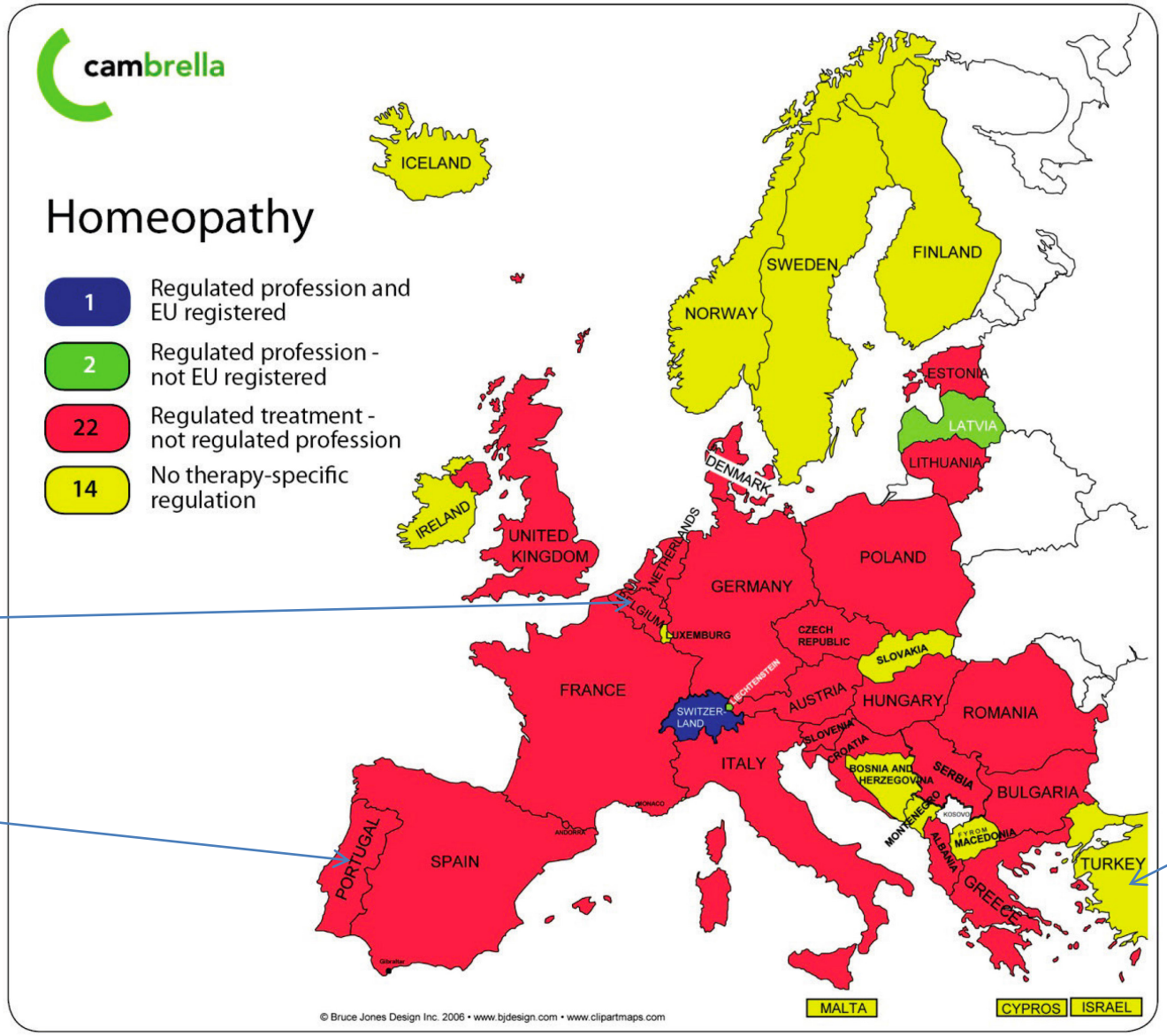
Portugal- new profession

Turkey: new law

nafkam The National Research Center in Complementary and Alternative Medicine

UNIVERSITY OF TROMSØ

UiT / THE ARCTIC UNIVERSITY OF NORWAY



Belgium New: Only doctors

Portugal- New profession

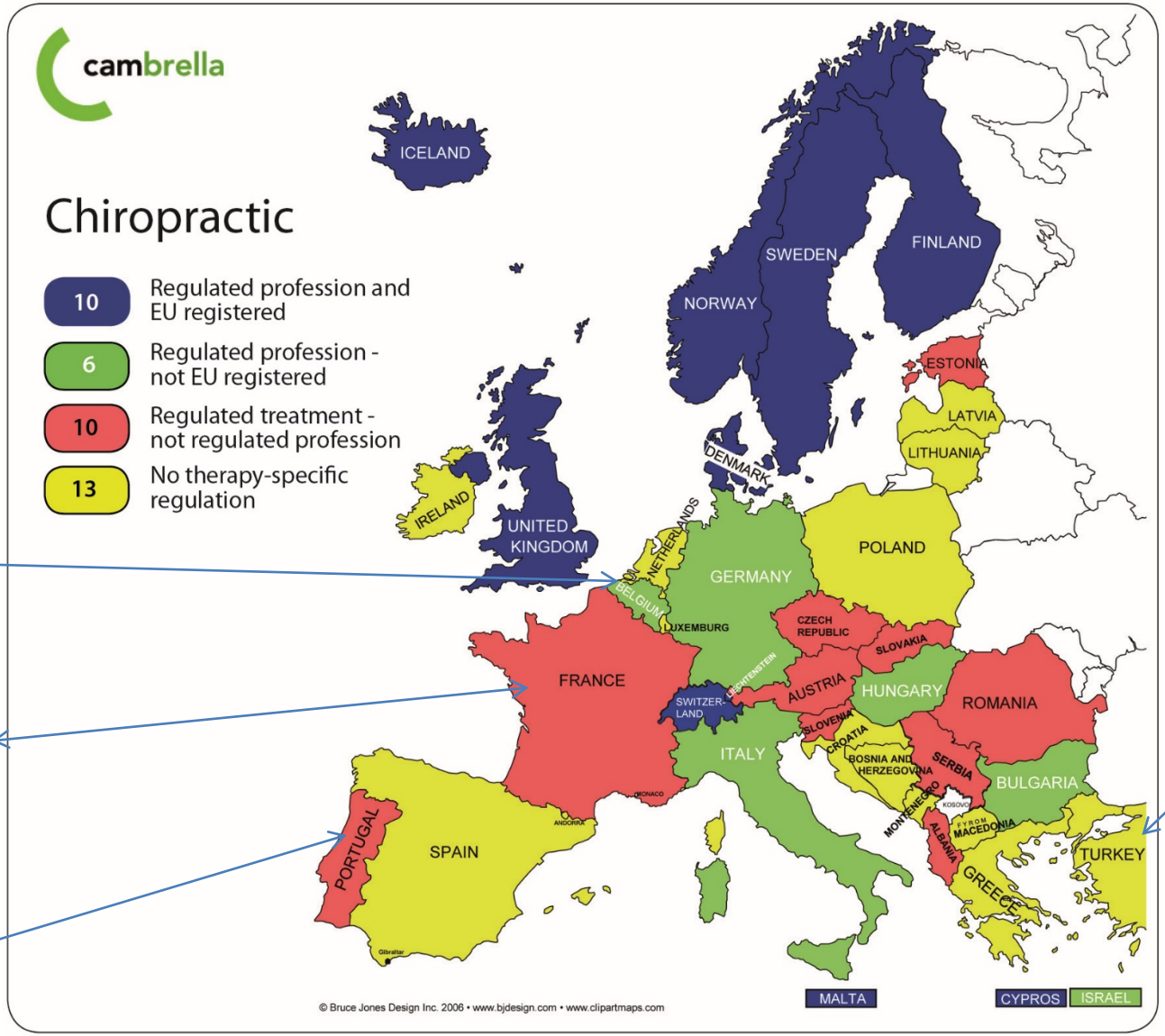
Turkey: New profession

nafkam The National Research Center in Complementary and Alternative Medicine

UNIVERSITY OF TROMSØ
UiT / THE ARCTIC UNIVERSITY OF NORWAY

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.



Belgium : New profession

France: New: EU-registered profession

Portugal: New profession

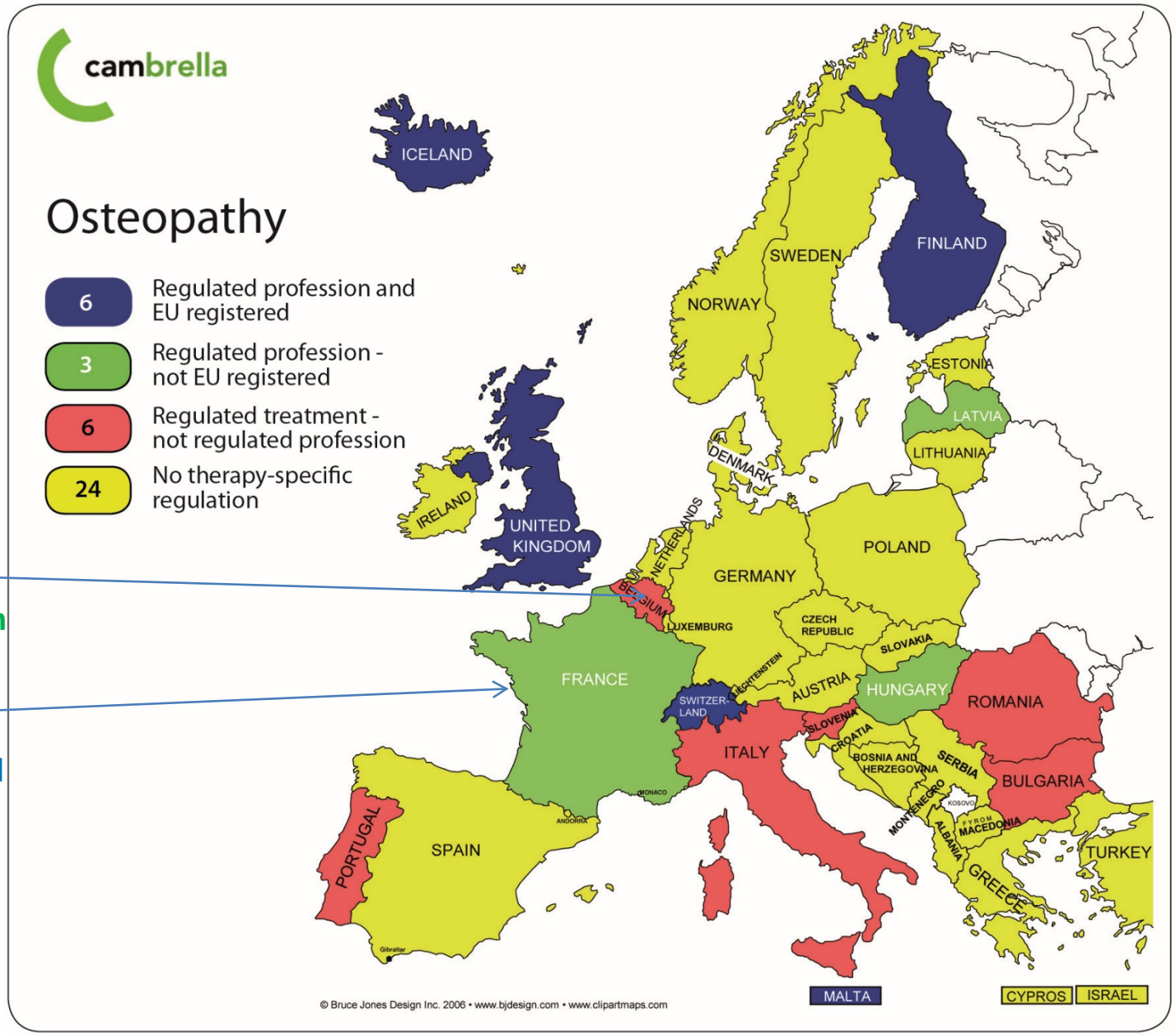
Turkey: New regulation-medical profession

nafkam The National Research Center in Complementary and Alternative Medicine

UNIVERSITY OF TROMSØ
UiT / THE ARCTIC UNIVERSITY OF NORWAY

Belgium: New regulation

France: New: Eu-registered



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

cambrella

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

Master thesis:

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

nafkam The National Research Center in Complementary and Alternative Medicine

UNIVERSITY OF TROMSØ

UiT / THE ARCTIC UNIVERSITY OF NORWAY

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

Subscribe to «News»

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