



# **Legal issues for mHealth in Europe. An overview**

**Stefaan Callens**





## Apps and health care systems

- Globalization and individualisation (right to make an informed choice)
- Impact of mHealth on health law



## Existing Legal Framework

- TFEU
- Directive 95/46 – Draft Regulation
- Directive 98/34
- Directive 2002/58
- Directive 2000/31
- Directive 2007/47 – Draft Regulation
- Directive 1997/7
- Directive 2011/24
- Rome I and Rome II regulations
- ...



## **Short term legal action is needed**

- Liability rules?
- Specific licensing scheme?
- Informed consent?



## **Long term action**

- Challenges for health care practitioners and hospitals
- Reimbursement of mHealth
- Relationship between patients and the industry