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Introduction to the European legal framework for eHealth

Telemedicine services

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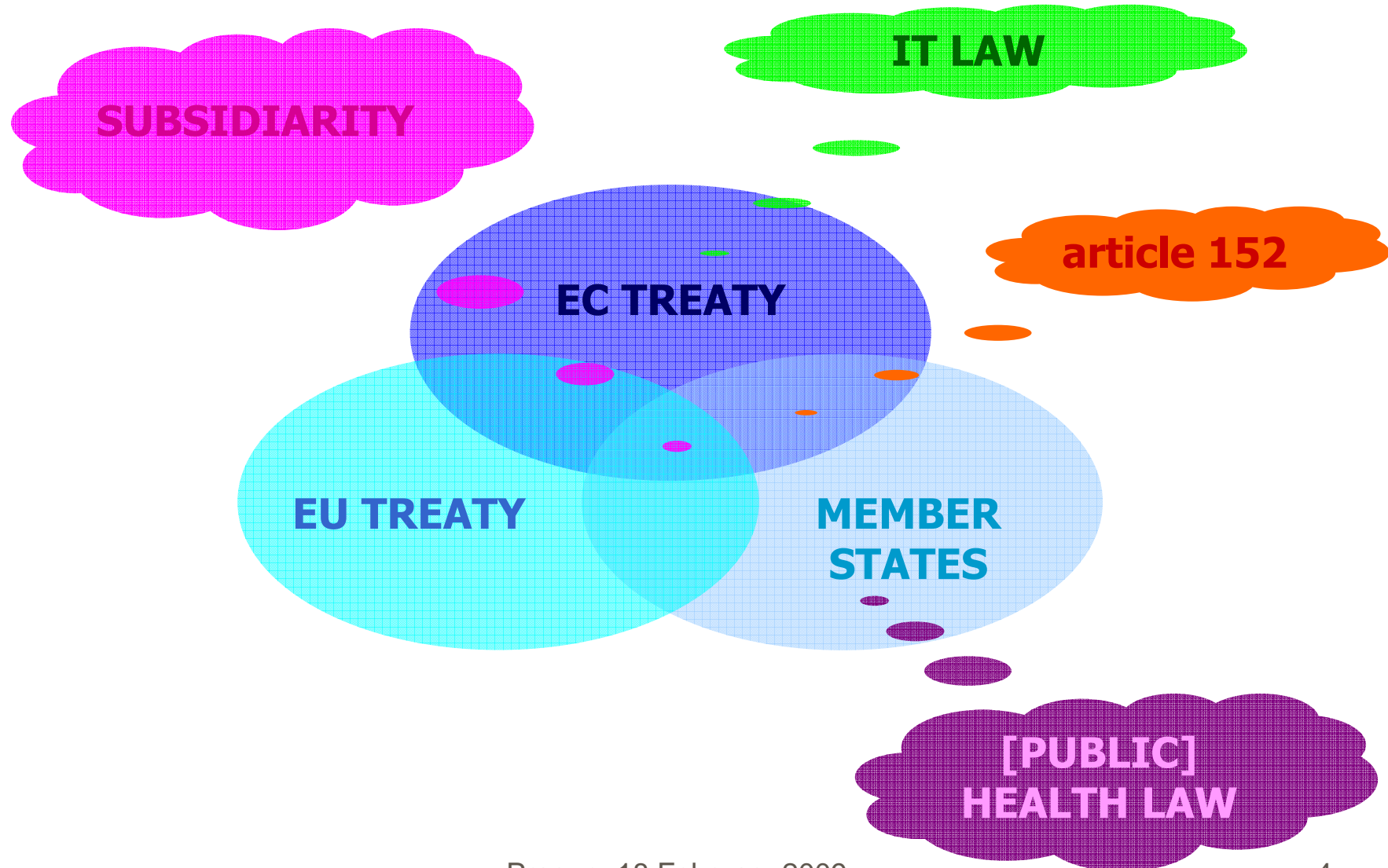
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AREAS OF COMPETENCE

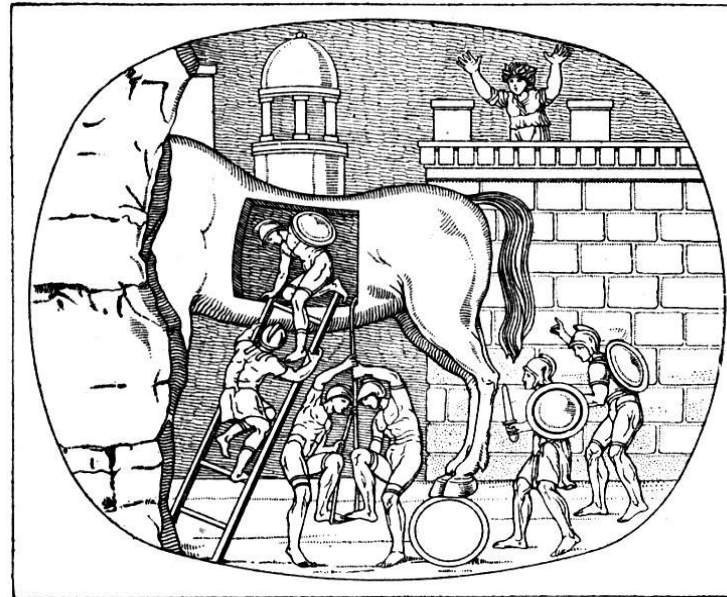


Prague, 18 February 2009





**COM(2008)415 final
'patient's rights in
cross-border
healthcare'**



**COM(2008)3828
final 'Cross
border
interoperability
of electronic
health record
systems'**

**COM(2008)689 final 'telemedicine for the
benefit of patients, healthcare systems
and society'**



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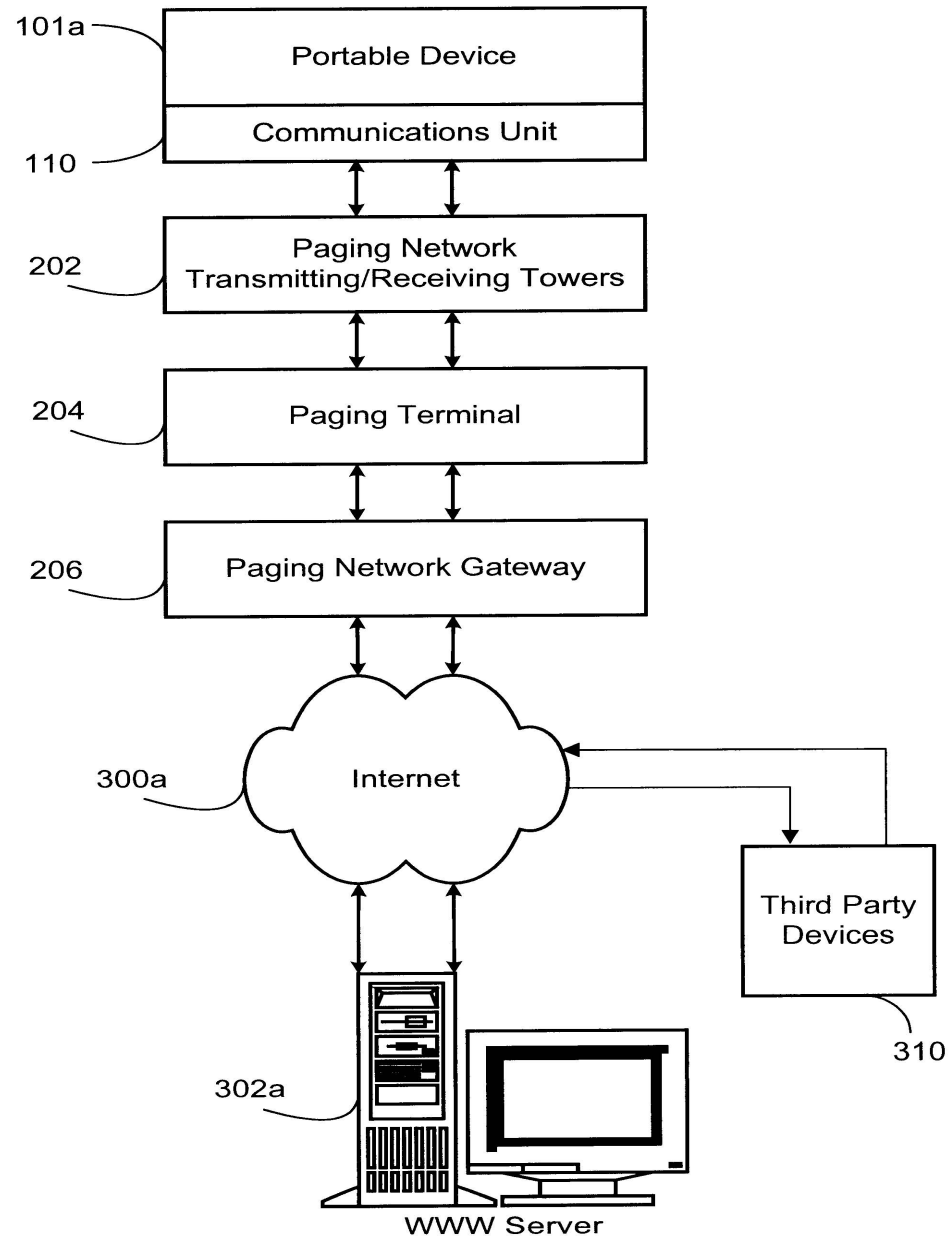


INFORMATION MANAGEMENT

Prague, 18 February 2009

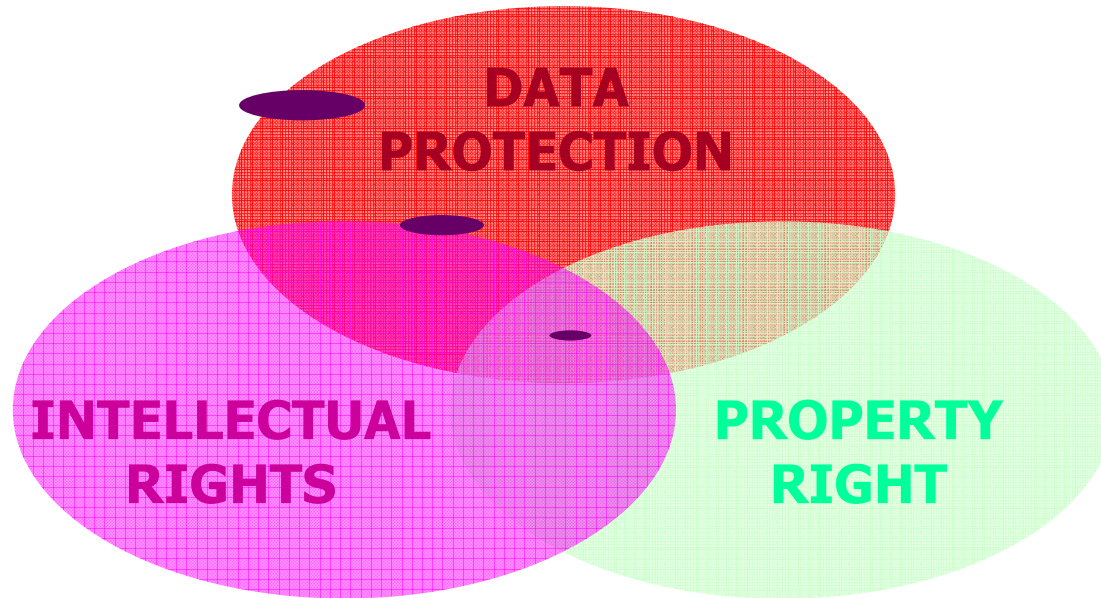
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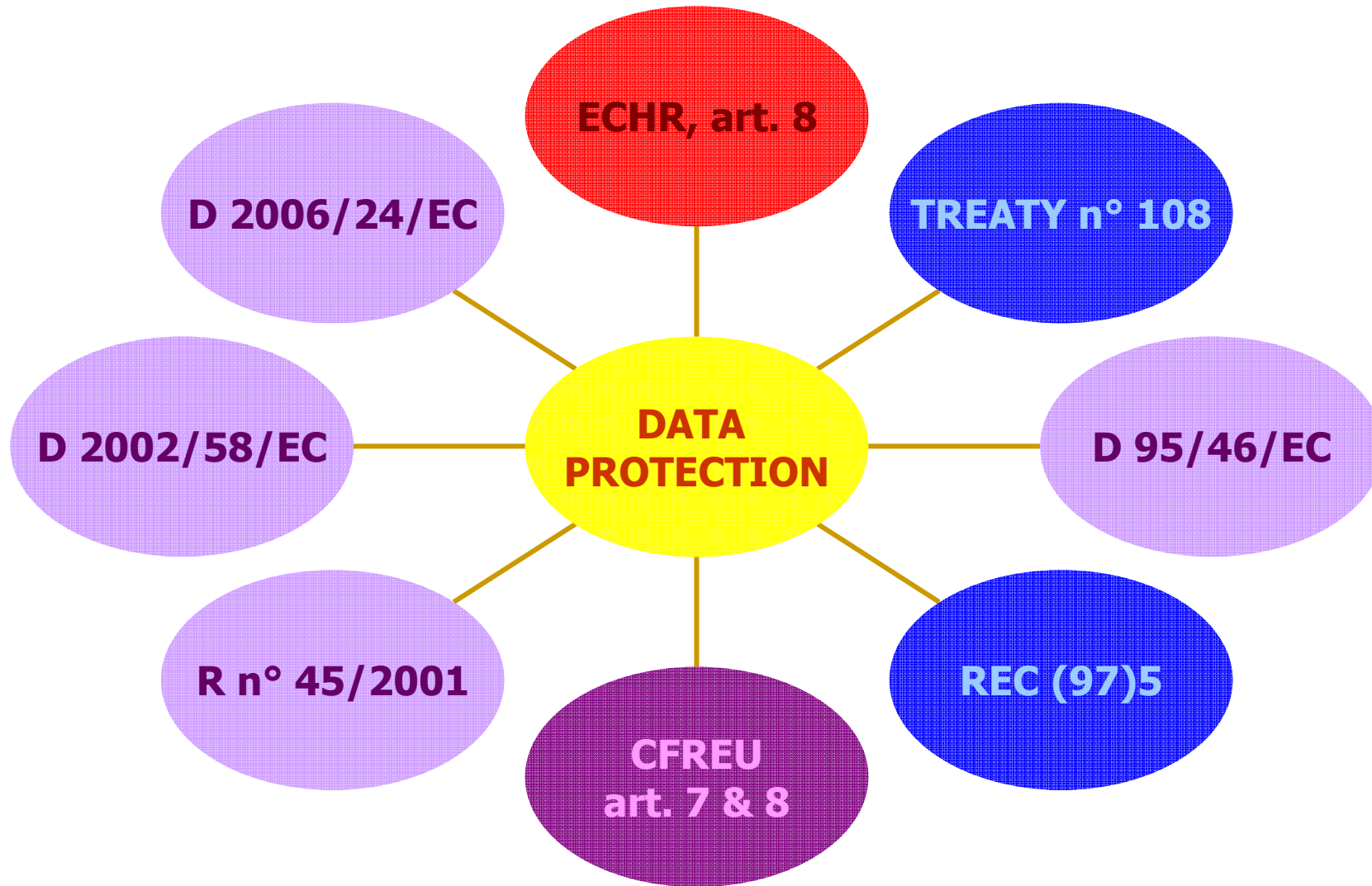


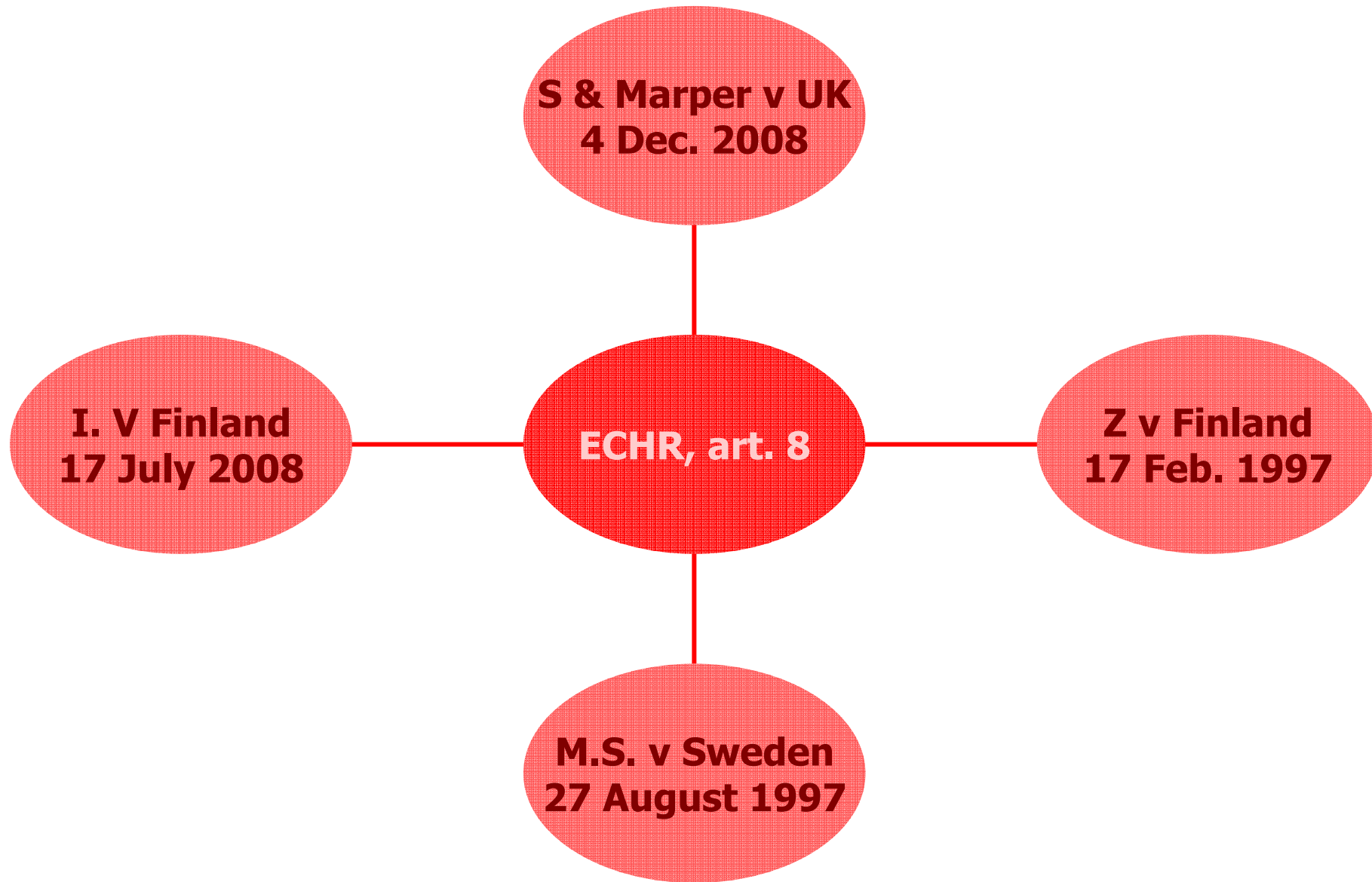


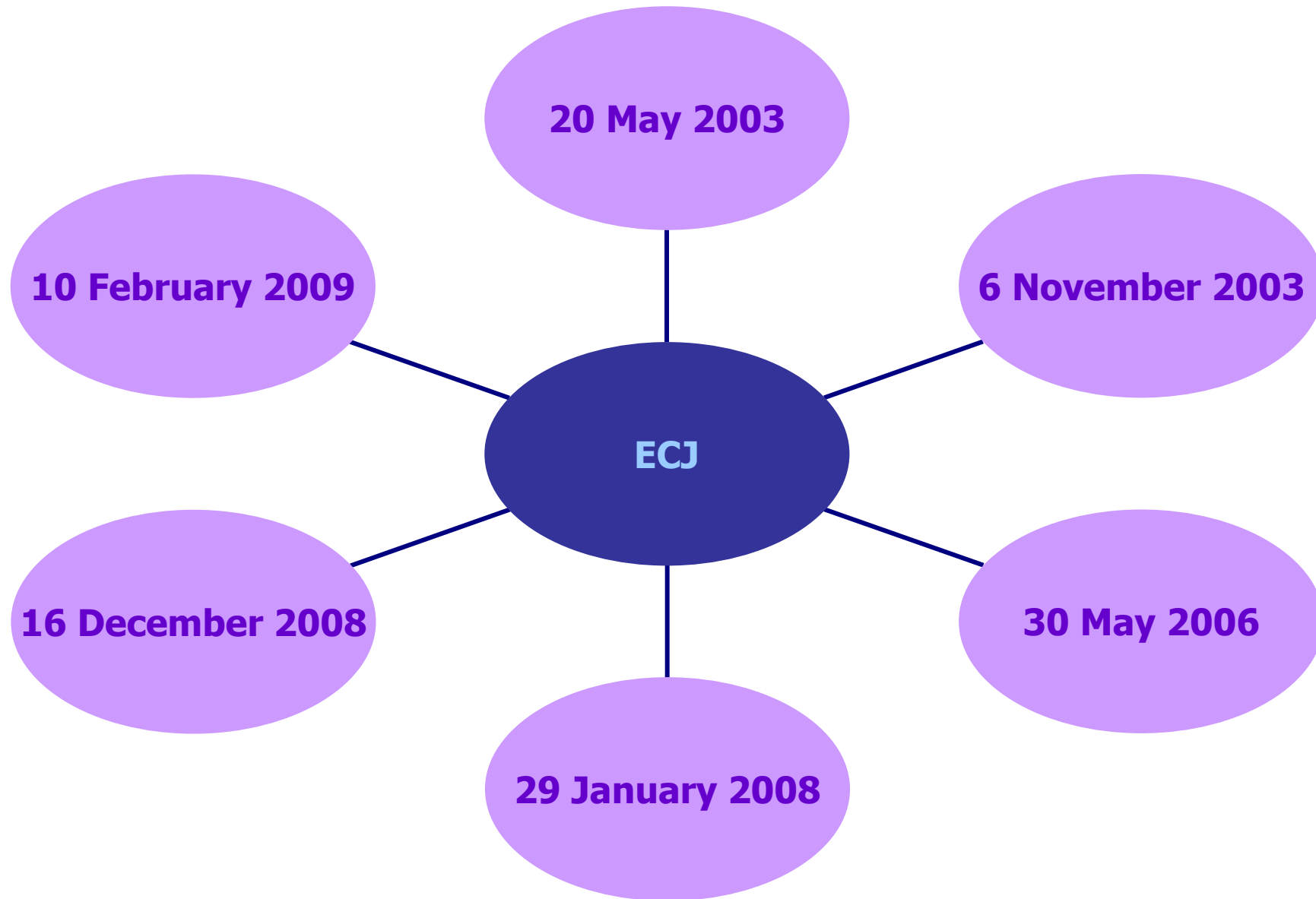


OLD QUARRELS











Processing of Personal Data (Data Protection)

1. European Convention on Human Rights, art. 8.
2. Charter of Fundamental Rights of the European Union, art. 7 & 8
3. Convention for the Protection of Individuals with Regard to Automatic Processing of Personal Data (Council of Europe, European Treaty Series, n° 108, Strasbourg, 28 Jan. 1981)
4. Directive 95/46/CE of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data



- 5.** Regulation (EC) No. 45/2001 on the protection of individuals with regard to the processing of personal data by the Community, institutions, and bodies, and on the free movement of such data
- 6.** Directive 2002/58/EC of the European Parliament and of the Council of 12 July 2002 concerning the processing of personal data and the protection of privacy in the electronic communications sector (Directive on privacy and electronic communications)
- 7.** Directive 2006/24/EC of the European Parliament and of the Council of 15 March 2006 on the retention of data generated or processed in connection with the provision of publicly available electronic communications services or of public communications networks and amending Directive 2002/58/EC



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European Court of Human Rights

- E.C.H.R., 4 December 2008, *S. & Marper v. United Kingdom*.
- E.C.H.R., 25 February 1997, *Z. v. Finland*.
- E.C.H.R., 27 August 1997, *M.S. v. Sweden*.
- E.C.H.R., 17 July 2008, *I. v. Finland*.



European Court of Justice

- E.C.J., 10 February 2009, Ireland & Slovak Republic v. European Parliament, the Council of the European Union, the Kingdom of Spain, the Kingdom of the Netherlands, the Commission of the European Communities & the European Data Protection Supervisor, Case C-301/06.
- E.C.J., 16 December 2008, Tietosuoja-valtuutettu v. Satakunnan Markkinapörssi Oy, Satamedia Oy, Case C-73/07.
- E.C.J., 29 January 2008, Productores de Musica de Espana (Promusicae) v. Telefonica de Espana SAU, Case C-275/06;
- E.C.J., 30 May 2006, European Parliament v. Council of the European Union and Commission of the European Communities, Joined Cases C-317/04 and C-318/04;
- E.C.J., 6 November 2003, Bodil Lindqvist v. Sweden, case C-101/01;
- E.C.J., 20 May 2003, Rechnungshof v. Österreichischer Rundfunk and Others and Christa Neukomm and Joseph Lauer mann v. Österreichischer Rundfunk, Joined Cases C-465/00, C-138/01 and C-139/01.



Court of First Instance

- C.F.I., 8 November 2007, Bavarian Lager v. Commission of the European Communities, Case T-194/04.
- C.F.I., 12 September 2007, Kalliopi Nikolaou v. Commission of the European Communities, Case T-259/03.



Data Protection Working Party (art. 29) :

- Opinion 4/2007 on the concept of personal data (WP 136), adopted on 20th June 2007.
- Working Document on the processing of personal data relating to health in electronic health records (EHR) (WP 131), adopted on 15 February 2007.



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European Group on Ethics in Science and New Technologies

Ethical issues of healthcare in the information society.

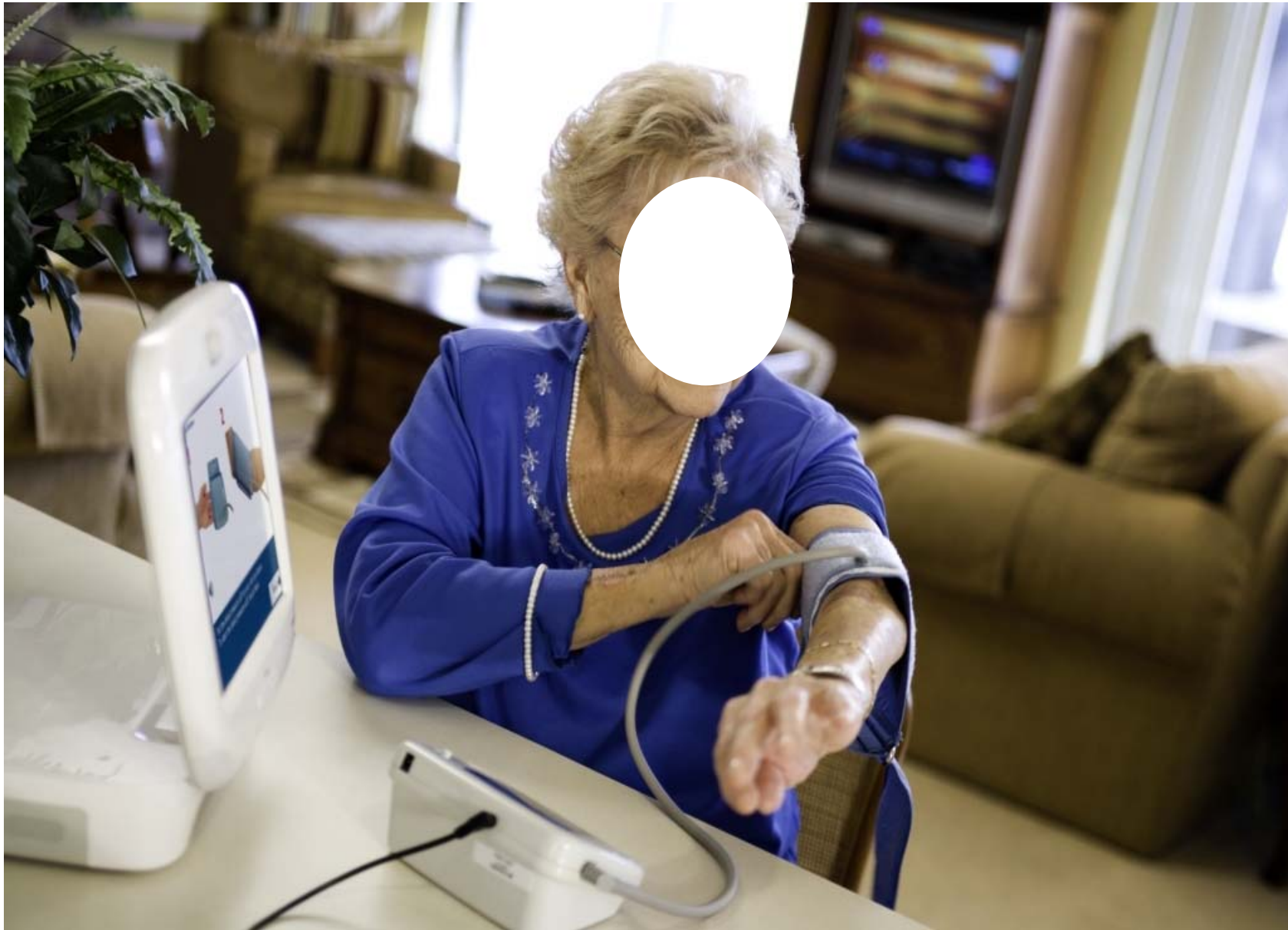
(Opinion n° 13 to the European Commission, 30 July 1999)

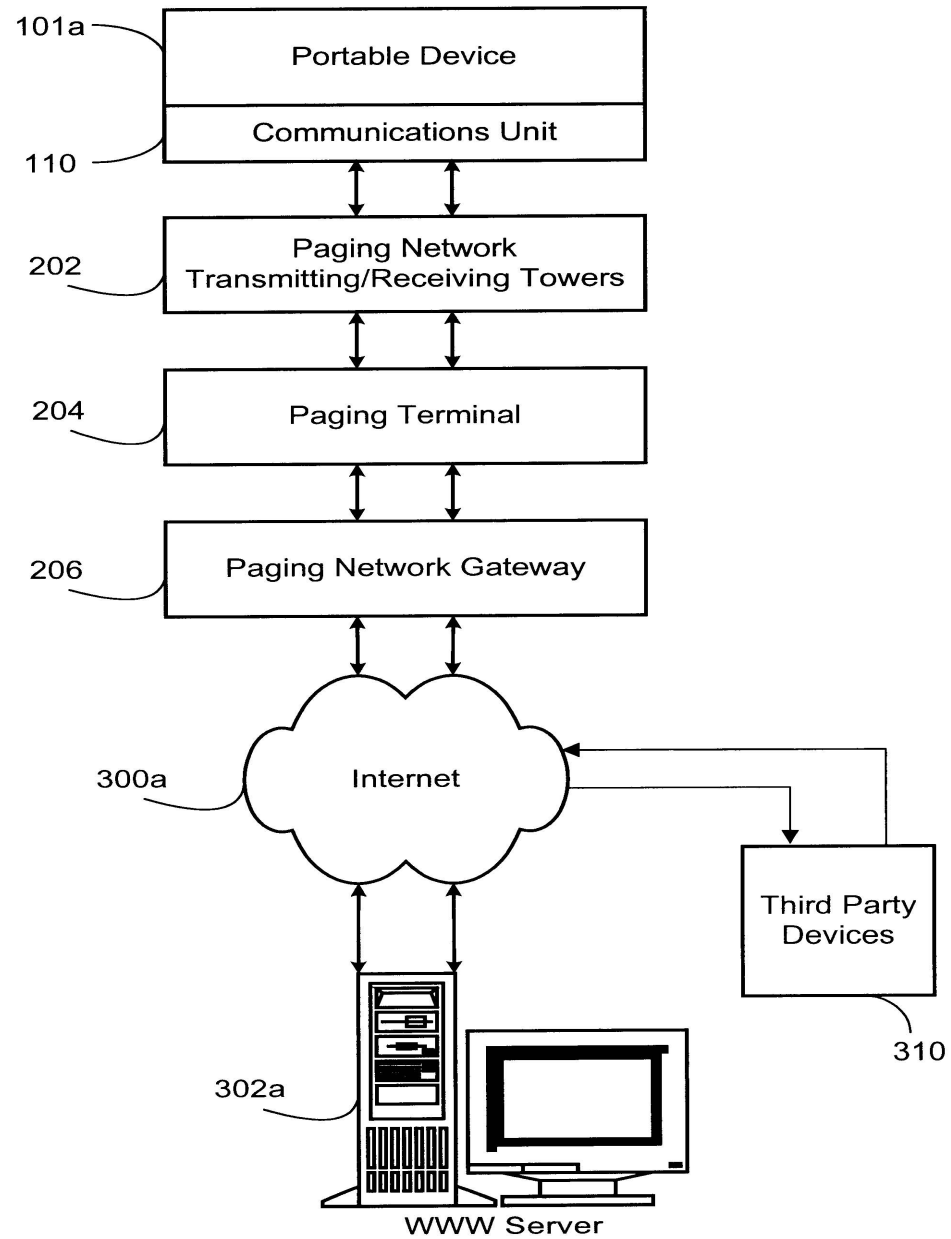


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PRODUCTS AND EQUIPMENTS







General product safety

Hazardous substances in EE equipment

WEEE

Radio equipment & telecom terminal

Medical devices



Implantable medical devices

Medical devices

Electromagnetic compatibility

In vitro diagnostic medical devices

Voltage limits

Ionizing radiation



Directive 2002/58/EC (Directive on privacy and electronic communications), **art. 14.3** (technical features and standardisation) :

« Where required, measures may be adopted to ensure that terminal equipment is constructed in a way that is compatible with the right of users to protect and control the use of their personal data, in accordance with Directive 1999/5/EC and Council Decision 87/95/EEC of 22 December 1986 on standardisation in the field of information technology and communications »



1. General product safety

Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety

2. Hazardous substances in electrical and electronic equipment

Directive 2002/95/EC of the European Parliament and of the Council of 27 January 2003 on the restriction of the use of certain hazardous substances in electrical and electronic equipment



3. WEEE

Directive 2002/96/EC of the European Parliament and of the Council of 27 January 2003 on waste electrical and electronic equipment (WEEE)

4. Radio equipment and telecommunications terminal

Directive 1999/5/EC of the European Parliament and of the Council of 9 March 1999 on radio equipment and telecommunications terminal equipment and the mutual recognition of their conformity



5. Electromagnetic compatibility

Directive 2004/108/EC of the European Parliament and of the Council of 15 December 2004 on the approximation of the laws of the Member States relating to electromagnetic compatibility and repealing Directive 89/336/EEC Text with EEA relevance



6. Voltage limits

Directive 2006/95/EC of the European Parliament and of the Council of 12 December 2006 on the harmonization of the laws of Member States relating to electrical equipment designed for use within certain voltage limits



7. Medical devices

- Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active **implantable medical devices**
- Council Directive 93/42/EEC of 14 June 1993 concerning **medical devices**
- Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on **in vitro diagnostic medical devices**



8. Ionizing radiation

Council Directive 97/43/Euratom of 30 June 1997 on health protection of individuals against the dangers of ionizing radiation in relation to medical exposure, and repealing Directive 84/466/Euratom



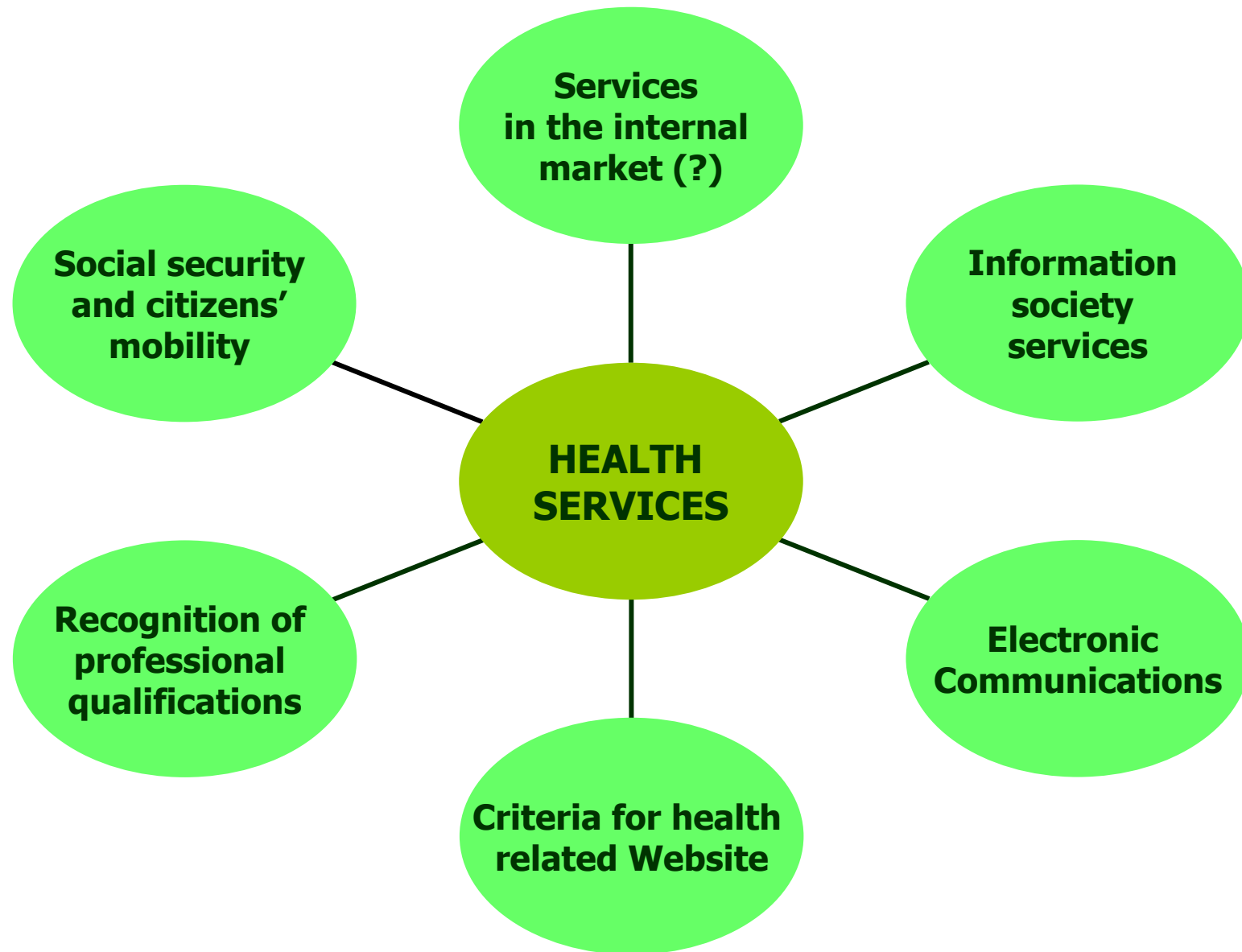
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PROVISION OF HEALTH SERVICES WITHIN THE EUROPEAN COMMUNITY

Prague, 18 February 2009

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eCOMMERCE
[information society
services]



Websites of doctors promoting their activities ?

Online selling of drugs (ePharmacy) ?

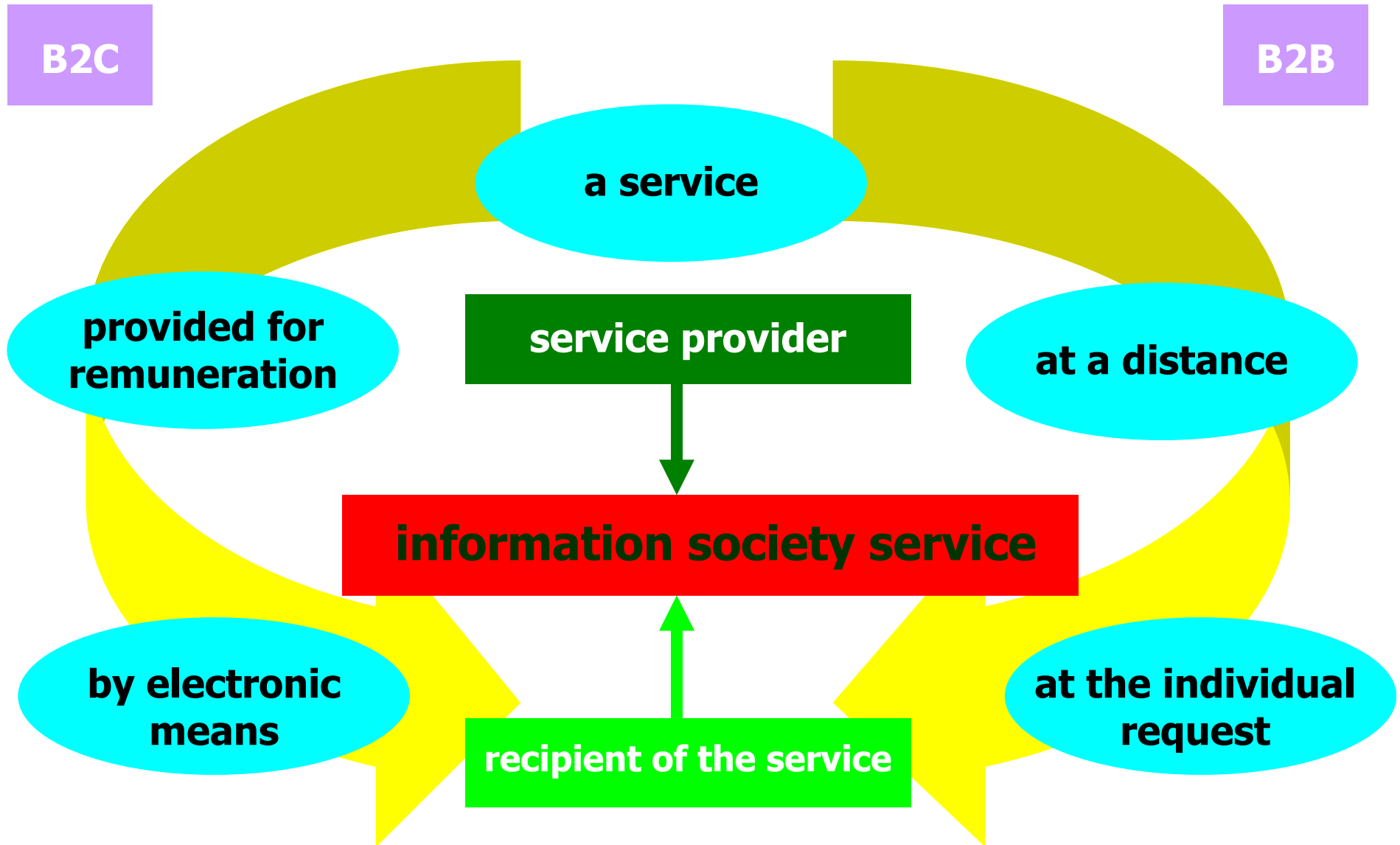
Online advice requiring no physical examination ?

Remote medical monitoring ?

Remote medical imaging ?

Online access to HER ?

Online databases accessible for practitioners or patients ?



REGARDING « APPLICABLE LAW »



**Nurse practitioner
in Italy**



**Practitioner
in Belgium**

Country of origin

REGARDING INFORMATION



**Nurse practitioner
in Italy**

- ✓ **Name of the nurse**
- ✓ **Geographic address of the nurse**
- ✓ **Other details of the nurse allowing for direct and effective contact**
- ✓ **Registration information**
- ✓ **Supervisory authority**
- +
- ✓ **Registration information for regulated professions**
- ✓ **Professional title and the Member State where it has been granted**
- ✓ **Applicable professional rules**

REGARDING COMMERCIAL COMMUNICATIONS



**Nurse practitioner
in Italy**

- ✦ **Commercial communications**
- ✦ **Unsolicited commercial communication**
- ✦ **Commercial communications from regulated professions**



REGARDING eCONTRACT



**Nurse practitioner
in Italy**

**Information to provide
to the recipient**

Placing of the order



REGARDING EXONERATION OF LIABILITY

**NO MONITORING
DUTY**

MERE CONDUIT

CACHING

HOSTING



1. Services in the internal market

Directive 2006/123/EC of the European Parliament and of the Council of 12 December 2006 on services in the internal market

2. Information Society Services

Directive 2000/31/EC of the European Parliament and of the Council of 8 June 2000 on certain legal aspects of information society services, in particular electronic commerce, in the Internal Market (Directive on electronic commerce)



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On the notion of information society services :

Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998 laying down a procedure for the provision of information in the field of technical standards and regulations



3. Regulation of electronic communications

- Directive 2002/20/EC of the European Parliament and of the Council of 7 March 2002 on the authorisation of electronic communications networks and services (**Authorisation Directive**)
- Directive 2002/21/EC of the European Parliament and of the Council of 7 March 2002 on a common regulatory framework for electronic communications networks and services (**Framework Directive**)
- Directive 2002/22/EC of the European Parliament and of the Council of 7 March 2002 on universal service and users' rights relating to electronic communications networks and services (**Universal Service Directive**)



4. Quality criteria for Health related Website

Communication from the Commission to the Council, the European Parliament, the Economic and Social Committee and the Committee of the Regions - eEurope 2002: Quality Criteria for Health related Websites



5. Recognition of professional qualifications

Directive 2005/36/EC of the European Parliament and of the Council of 7 September 2005 on the recognition of professional qualifications



6. Social security and citizens' mobility

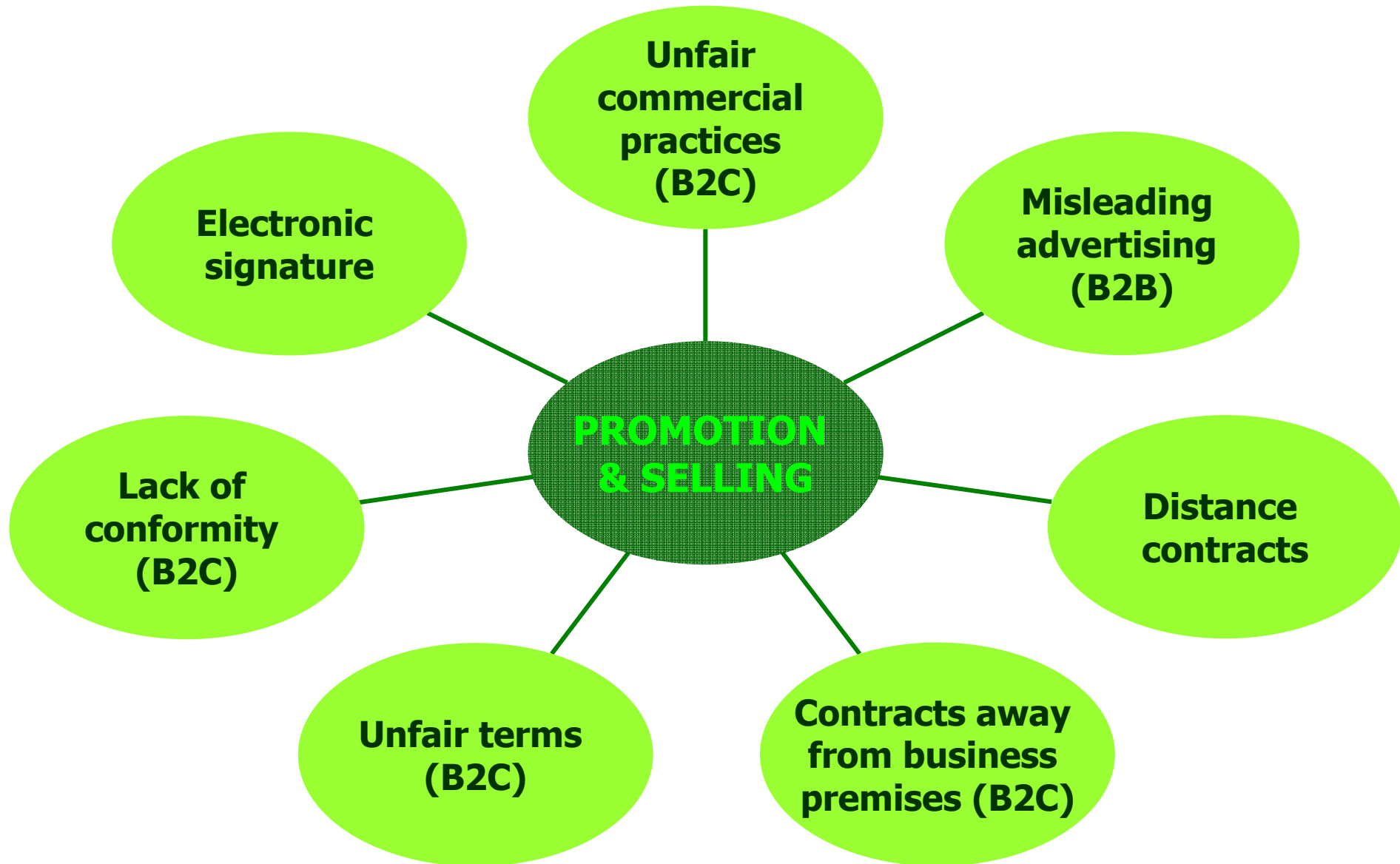
Regulation (EEC) No 1408/71 of the Council of 14 June 1971 on the application of social security schemes to employed persons and their families moving within the Community



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Promotion and selling of products and services





1. Unfair Commercial Practices (B2C)

Directive 2005/29/EC of the European Parliament and of the Council of 11 May 2005 concerning unfair business-to-consumer commercial practices in the internal market and amending Council Directive 84/450/EEC, Directives 97/7/EC, 98/27/EC and 2002/65/EC of the European Parliament and of the Council and Regulation (EC) No 2006/2004 of the European Parliament and of the Council (Unfair Commercial Practices Directive)



2. Misleading advertising (B2B)

Council Directive 84/450/EEC of 10 September 1984 relating to the approximation of the laws, regulations and administrative provisions of the Member States concerning misleading advertising



3. Distance contracts and contracts negotiated away from business premises (B2C)

- Directive 1997/7/EC of the European Parliament and of the Council of 20 May 1997 on the Protection of Consumers in respect of Distance Contracts
- Council Directive 85/577/EEC of 20 December 1985 to protect the consumer in respect of contracts negotiated away from business premises



4. Unfair terms (B2C)

Council Directive 93/13/EEC of 5 April 1993 on unfair terms in consumer contracts

5. Electronic signature

Directive 1999/93/EC of the European Parliament and of the Council of 13 December 1999 on a Community framework for electronic signatures



6. Lack of conformity (B2C)

Directive 1999/44/EC of the European Parliament and of the Council of 25 May 1999 on certain aspects of the sale of consumer goods and associated guarantees



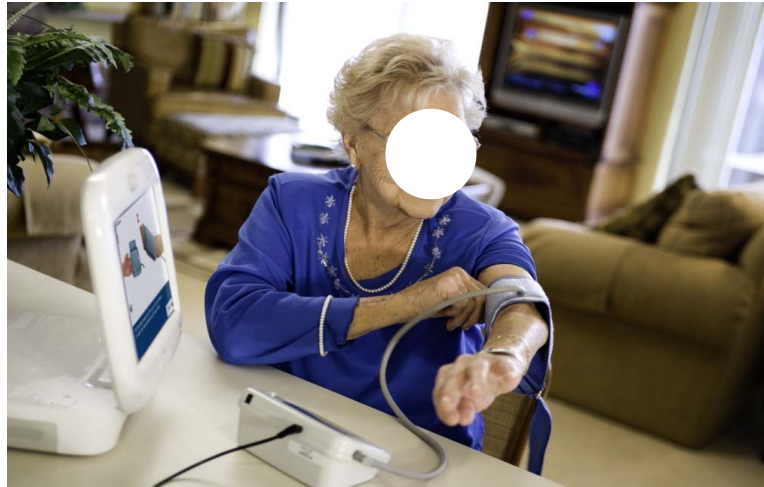
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LIABILITY

Prague, 18 February 2009

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Council Directive 85/374/EEC of 25 July 1985 on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products

[+ liability of the data controller]



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LITIGATION



1. International jurisdiction

Council Regulation (EC) n° 44/2001 of 22 December 2000 on jurisdiction and the recognition and enforcement of judgments in civil and commercial matters



2. Applicable law

- Rome Convention on the law applicable to contractual obligations (1980)
- Regulation (EC) n° 864/2007 of the European Parliament and of the Council of 11 July 2007 on the law applicable to non-contractual obligations (Rome II)
- Regulation (EC) n° 593/2008 of the European Parliament and the Council of 17 June 2008 on the law applicable to contractual obligations (Rome I)



3. Recognition and enforcement of judgments

Council Regulation (EC) n° 44/2001 of 22 December 2000 on jurisdiction and the recognition and enforcement of judgments in civil and commercial matters



4. Service of judicial and extrajudicial documents

Regulation (EC) n° 1393/2007 of the European Parliament and of the Council of 13 November 2007 on the service in the Member States of judicial and extrajudicial documents in civil or commercial matters (service of documents), and repealing Council Regulation (EC) n° 1348/2000

[see also Council Regulation (EC) n° 1206/2001 of 28 May 2001 on cooperation between the courts of the Member States in the taking of evidence in civil or commercial matters]



5. Injunctions, Small Claims and Order for payment

- Directive 98/27/EC of the European Parliament and of the Council of 19 May 1998 on injunctions for the protection of consumers' interests
- Regulation (EC) No 861/2007 of the European Parliament and of the Council of 11 July 2007 establishing a European Small Claims Procedure
- Regulation (EC) No 1896/2006 of the European Parliament and of the Council of 12 December 2006 creating a European order for payment procedure



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6. Combating late payment (B2B)

Directive 2000/35/EC of the European Parliament and of the Council of 29 June 2000 on combating late payment in commercial transactions



7. European enforcement order for uncontested claims

Regulation (EC) No 805/2004 of the European Parliament and of the Council of 21 April 2004 creating a European Enforcement Order for uncontested claims



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COMPETITION LAW



HEALTHCARE ?

HEALTH SERVICES ?

COM(2003)
270 final

COM(2004)
374 final

COM(2007)
725 final

**Services of
general interest**

**Social services of
general interest**

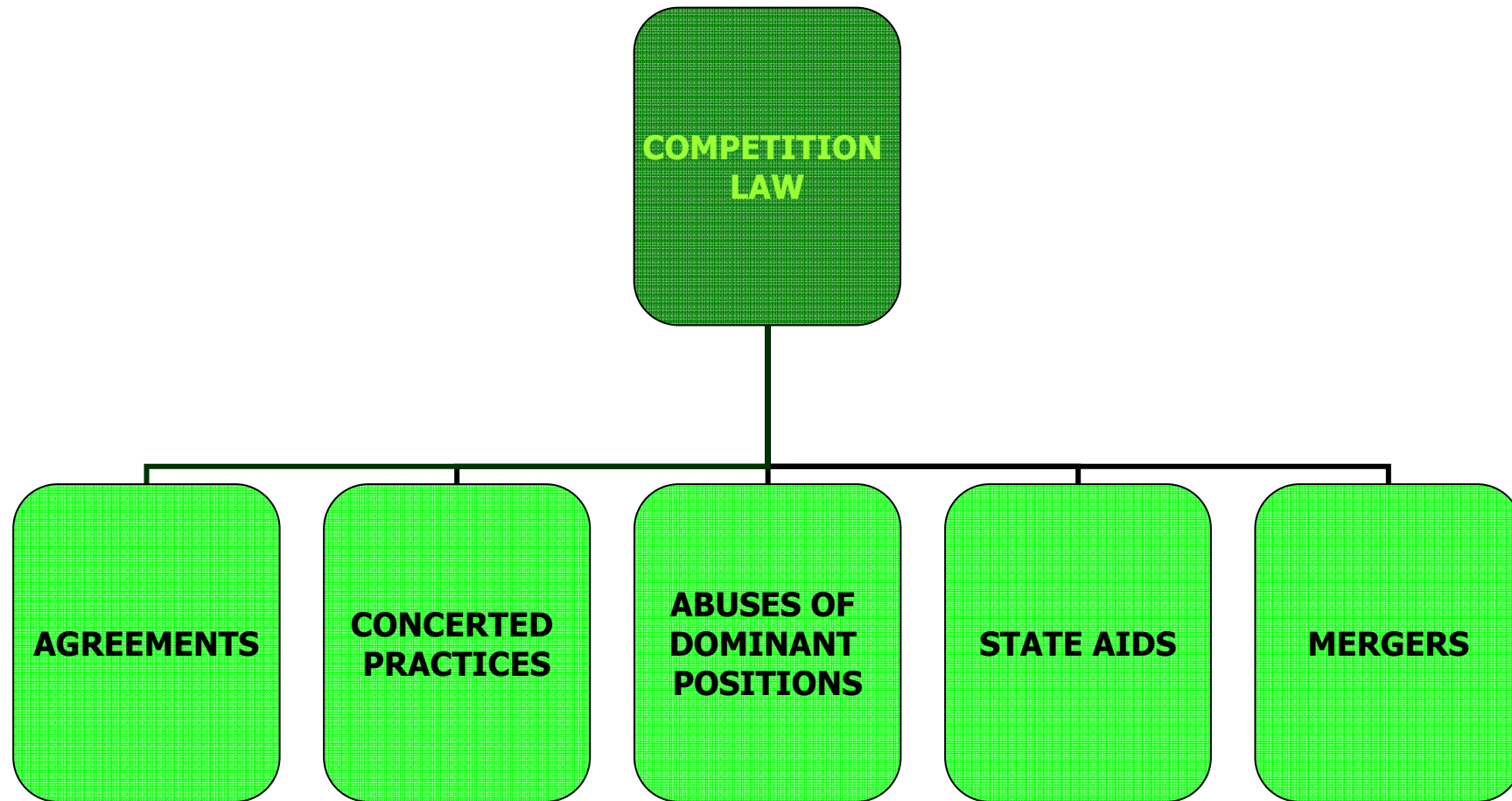
**COMPETITION
LAW ?**

**Services of
general economic
interest**

COM(2006)
177 final

art. 36
CFREU

art. 16 &
86.2
EC Treaty





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DISCUSSION



What could be missing in this legal framework ?

- Liability rules for service providers in healthcare ?
- Detailed requirements for the quality of e-Health products and services ?
- Free movement of health services ?
- Regulation of telematic infrastructures, etc. ?



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But is it the real problem with e-Health ?

What about the number of rules to take into account when creating or promoting or selling e-Health products and services, and what about their (**natural**) complexity ?



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The real problem with e-Health is the access to and the dissemination of the required legal knowledge for its deployment.



How could we remedy this situation ?

SHORT TERM

It is not easily conceivable to modify existing rules (except for minor changes) or to create new ones very quickly

- Plan legal studies (fundamental research and not only applied research or legal consultancy) for each project aiming at developing a new e-Health product or service



How could we remedy this situation ?

SHORT & MID TERM

- Adapt the education of the actors of e-Health (e.g. include special teaching on e-Health products and services) :
 - health practitioners,
 - lawyers (by ex. The DTIC program (Law Faculty of Namur) includes a teaching on *Medical Law and IT*),
 - computer scientists, etc.



How could we remedy this situation ?

MID TERM

- Promote legal guidelines for each type of e-Health products and services (kind of codes of conduct)
- We should think of new ways of disseminating legal knowledge

By instance :

- the European Summer School on Medical Law (organized by the french ARFDM)
- the European Association of Health Law (EAHL)
- the European Public Health Law Network (EPHLN)



How could we remedy this situation ?

MID & LONG TERM

- Regulatory work to be done (heavy)
- Allow for the possibility to sue the service provider before the court of the patient's residence (easy)
- Allow for the service provider to sue the patient only before the court of the patient's residence (with no other alternatives) (easy)
- Constitute a (public or private) guarantee for the patient aiming at covering damages resulting from e-Health products or services in case of insolvency of the service provider (easy?)



CRID'S BIRTHDAY (30 YEARS)

We are organizing the second part of the 4th Session of the European Summer School on Medical Law (ARFDM) on the topic :

“Technologies and Health : Law & Ethics”

Belgium, Namur, 6-8 July 2009

(first part in Toulouse, 1-10 July 2009, *Public Health Law issues in a transnational context and Introduction to Health law and Bioethics in Europe*)



For more details :

Jean HERVEG, "Panorama des responsabilités liées aux services et produits de la santé en ligne en droit européen", Bruxelles, Larcier, *Revue du Droit des Technologies de l'Information*, 2007/29, pp. 273-310

Jean HERVEG, "Overview on responsibilities regarding e-Health services and products in European Law", Bruxelles, Larcier, *Revue du Droit des Technologies de l'Information*, 2007/29, pp. 273- 310

Please, feel free to comment this paper and to complete this overview or to investigate further some of these issues



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THANK YOU FOR YOUR ATTENTION !

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