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Regulatory cooperation and harmonisation from the European Union perspective

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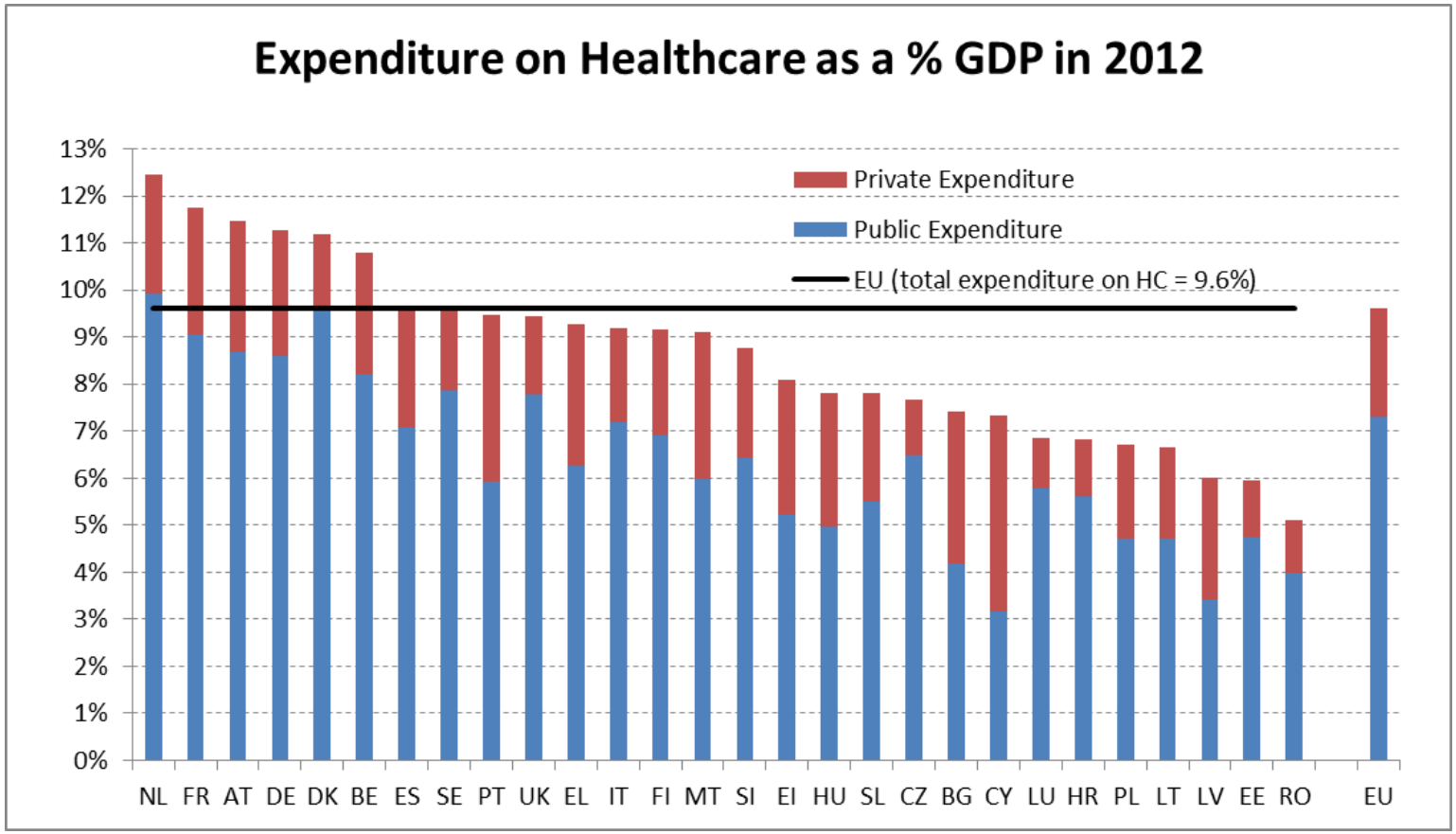
The European Union at a glance

A unique economic and political union between 28 sovereign European Countries

1957	***Founding Member States:*** Belgium, Germany, France, Italy, Luxembourg, Netherlands
	Enlargements
1973	United Kindom, Denmark, Ireland
1981	Greece
1986	Spain, Portugal
1995	Austria, Finland, Sweden
2004	Czech Republic, Estonia, Cyprus, Latvia, Lithuania, Hungary, Malta, Poland, Slovakia, Slovenia
2007	Bulgaria, Romania
2013	Croatia

"GDP footprint" of European health systems



Starting point: Legal basis for intervening in health systems

Art. 168 TFEU: Public Health
subsidiarity principle

Excerpt: "Union action, which shall complement national policies, shall be directed towards improving public health, preventing physical and mental illness and diseases, and obviating sources of danger to physical and mental health."

Internal Market legislation
affecting health services

- Directive on professional qualifications (2005/36)
- Directive on working times (2003/88)
- Directive on e-commerce (2000/31)
- General framework for European standardisation

What triggered growing EU intervention in health system?

Why

The economic and financial crisis, and the pressure on public finances

European Court's Jurisprudence on freedom to provide services

How

The European Semester

The economic adjustment programmes

Europe 2020

The adoption of the Directive on patients' rights in cross-border care

Cross-border Healthcare Directive: Headline messages

- Patients' rights to choose care and providers abroad confirmed, increased and clearly explained
- Information to patients on health systems and treatments
- Minimum set of patients' rights established in the EU

Patient Safety and Quality of Care

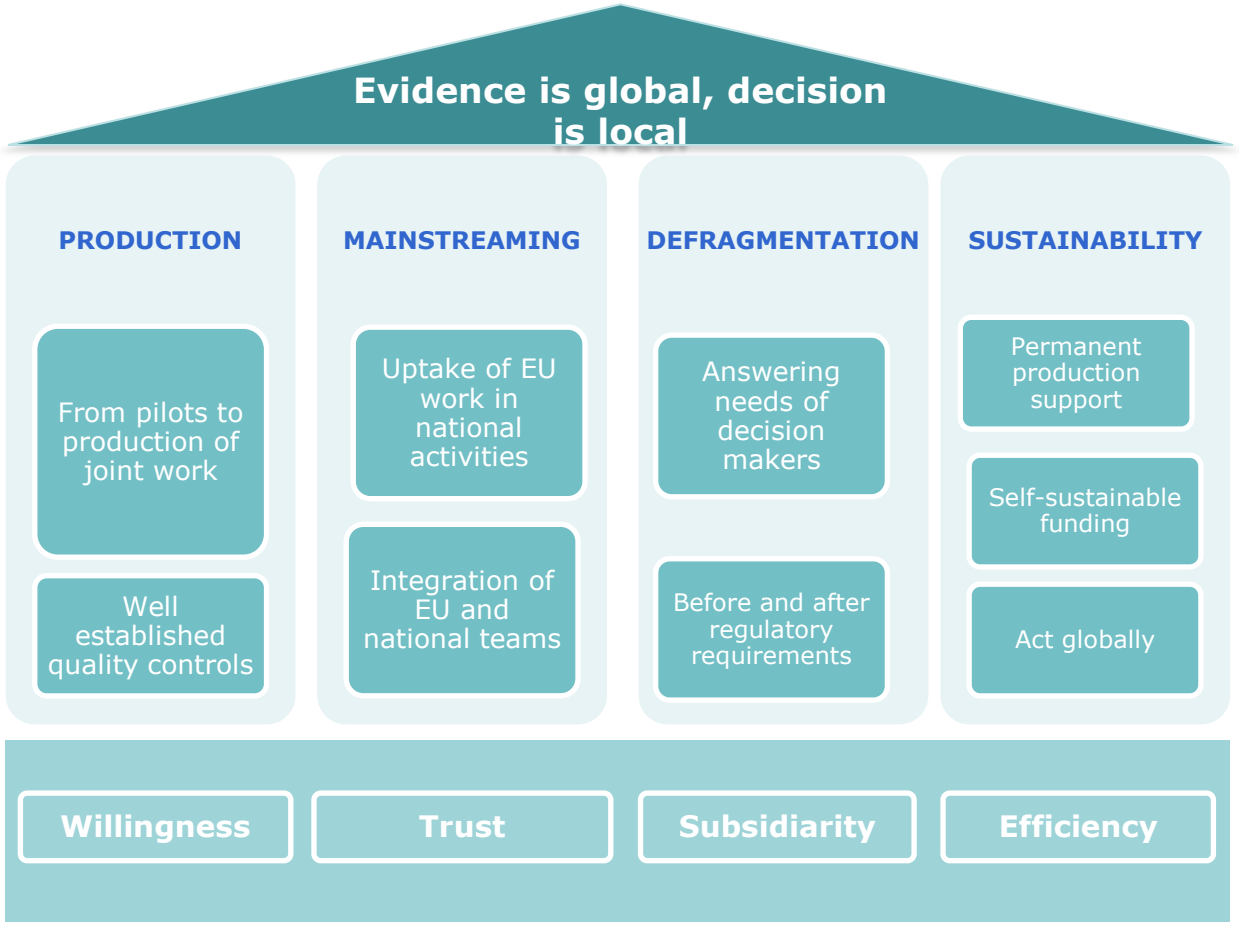
EU action: help Member States to coordinate their efforts to protect public health by:

- **Classifying and measuring patient safety *e.g.***
  - ✓ Co-financing of the Health Care Quality Indicators Project led by OECD
  - ✓ Agreement with WHO on delivering EU patient safety taxonomy

- **Sharing knowledge and experience *e.g.***
  - ✓ EU expert group on patient safety and quality of care
  - ✓ Co-financing of the EU network on patient safety and quality of care

- **Develop and promote research *e.g.***
  - ✓ Co-financing of projects within the Health Programme and Research programme FP7

The EU HTA Strategy

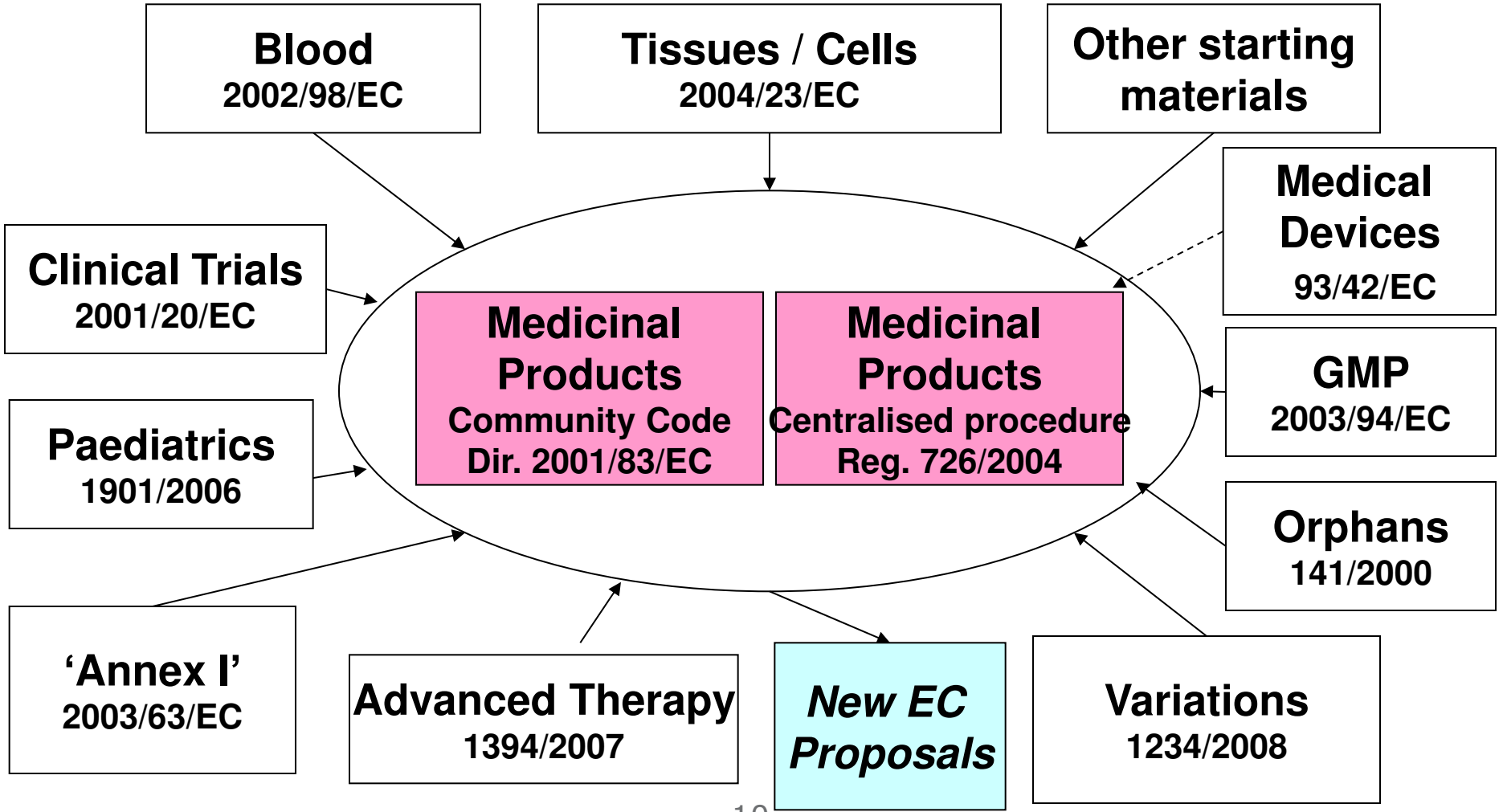


Sevala Malkic, 20th of April 2015

EU regulatory framework for medicinal products: Objectives

- To complete the single EU market for Pharmaceuticals
- To protect and promote public health and animal health
- To facilitate access by patients to new & better medicines
- To allow further development of European based R&D pharmaceutical industry
- To provide platform for discussion of public health issues at European level

The EU regulatory framework



EU legal framework for medical devices

- **Unlike medicines, medical devices are not subject to a marketing authorisation by a public authority.**
- **The current legal framework is based on 3 main directives:**

✓ **Directive 90/385/EEC on active implantable medical devices**
✓ **Directive 93/42/EEC on medical devices**
✓ **Directive 98/79/EC on in vitro diagnostic medical devices**

- **Their main objective is creation of an internal market for medical devices whilst ensuring a high level of protection of public health and patient safety.**
- **Prior to their placing on the market and depending on their risk classification, their conformity with the legal requirements is checked by notified bodies - via a procedure which is proportionate to the risk of the device.**
- **The low risk devices are certified by the manufacturers themselves.**
- **The EU medical device legislation is currently being revised.**

International cooperation: Beyond WHO

ICH: Harmonised tools for authorisation and pharmacovigilance

Main achievements:

- **60 guidelines (quality, safety, efficacy or multidisciplinary);**
- **MedDRA - international medical dictionary;**
- **Common format for marketing applications: CTD and eCTD.**

Reform ongoing: new ICH membership

Multilateral initiatives recently established/under development

- **International Coalition of Medicine Regulatory Authorities (ICMRA)**
- **International Pharmaceutical Regulators Forum (IPRF)**
- **International Generic Drug Regulatory Pilot (IGDRP)**
- **International Medical Device Regulators' Forum (IMDRF)**

Bilateral cooperation with strategic partners

- **Regulatory dialogue**
- **Mutual Recognition of GMP inspections**