European Society of Cardiology – Lessons learned from a decade of engagement

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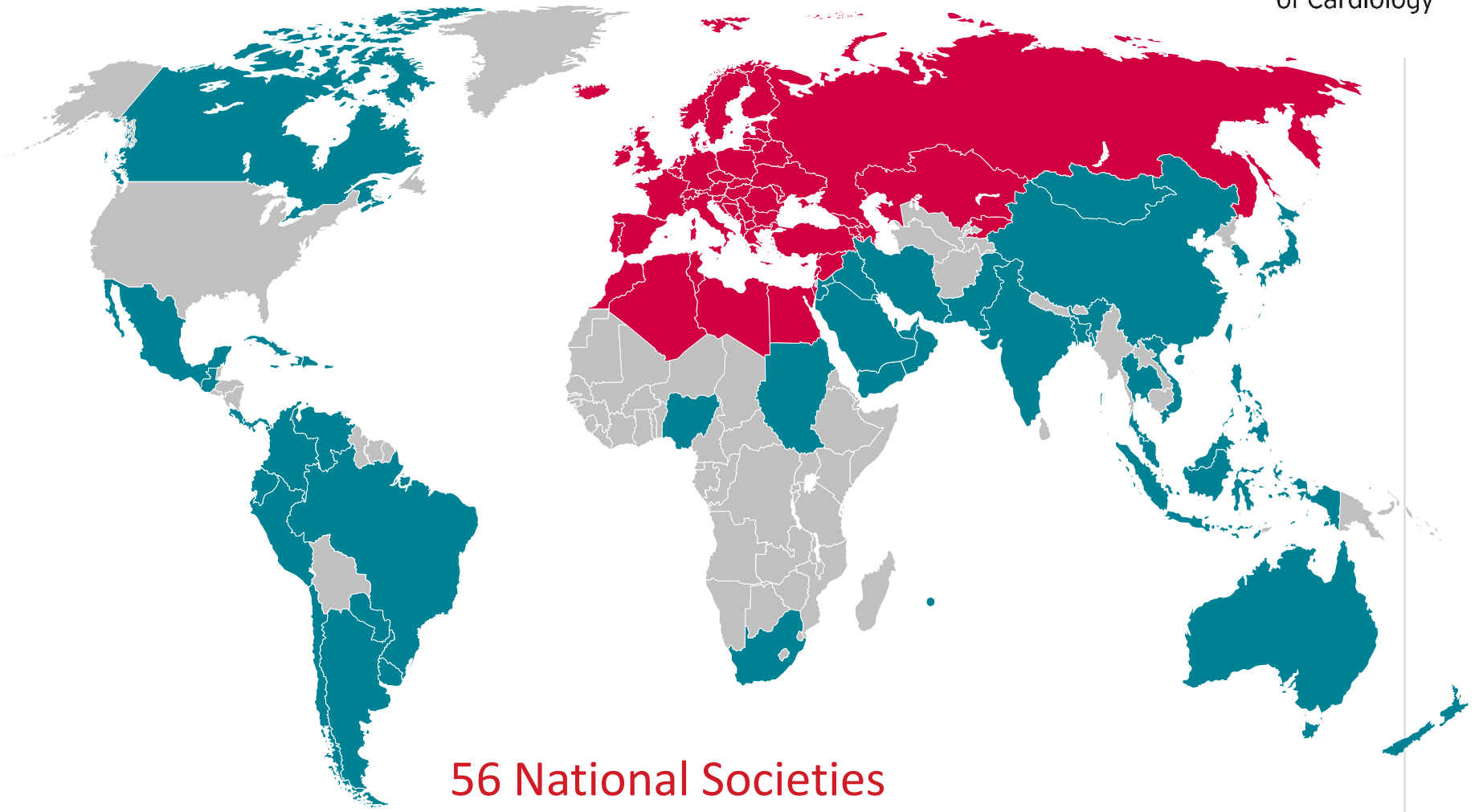
The European Society of Cardiology

ESC
European Society of Cardiology



56 National Societies

43 Affiliated National Societies

95,000 Health care professionals

27.2.2013 – Brussels Office

The European Heart Agency

ESC
European Society of Cardiology

ESC advocacy on medical devices

ESC
European Society of Cardiology

2008 ESC submission to public consultation on recast

2009 ESC participated in Exploratory Process at EC

2011 ESC Policy conference and paper in EHJ

2011 ESC participated in high-level conference on recast of the medical device directives

2011 Meeting with Chef du Cabinet of European Commissioner

2012 ESC invited by Commission to attend meetings of the **Clinical Investigation and Evaluation Working Group**

2013 Briefing meetings with MEPs and rapporteurs

2013 ESC invited to attend **Medical Devices Expert Group**

2014 ESC invited to attend **Vigilance Working Group ….**

2018 ESC invited to attend **Medical Devices Coordination Group**

2007 **<u>The Treaty of Lisbon</u>**

Paragraph 2 C (k)

Shared competence .. applies in .. ***common safety concerns in public health matters*** ..

The measures to be adopted ..must ..aim to set high standards of quality and safety where national standards affecting the internal market would otherwise prevent ***a high level of human health protection*** being achieved.

A standard approach for implementing EU law

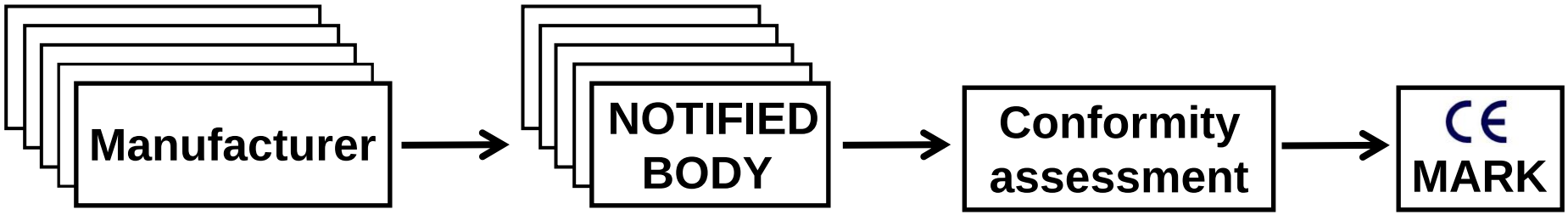
December 1984: The European Council agreed that it should take steps to complete the Internal Market, including implementation of European standards

1985 **Completing the Internal Market**
White Paper (85) 310

1985 **On a New Approach to Technical Harmonization and Standards**
Council Resolution 85/C 136/01

"National bodies authorized to issue marks or certificates of conformity shall be notified by each Member State to the Commission and to the other Member States."

Official Journal 4.6.85, C 136, p. 1–9



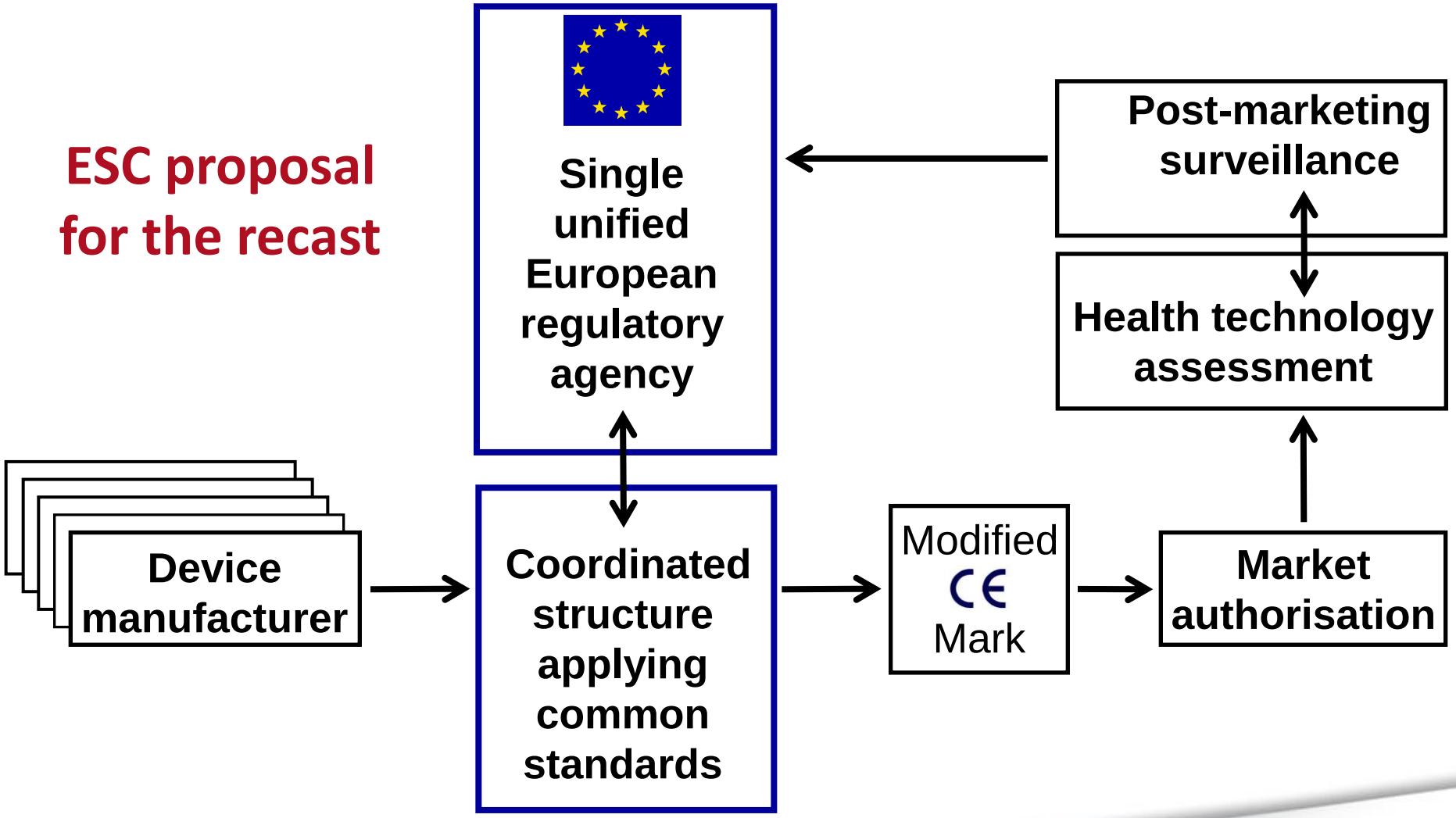
European Commission – Medical Devices

DG ENTR *Enterprise and industry*
DG SANCO *Health and consumer affairs (now DG SANTE)*
DG GROW *Internal Market, Industry, Entrepreneurship & SMEs*

DG JRC *Joint Research Centre (Ispra, Italy)*
DG SANTE *Inspections of notified bodies; health technology*
DG DIGIT *Development of Eudamed database*
DG CNECT *Medical software and apps*
DG RTD *Funding of research and development*
European Medicines Agency *Hybrid devices*

Eur Heart J 2011; 32: 1673-86

ESC proposal for the recast



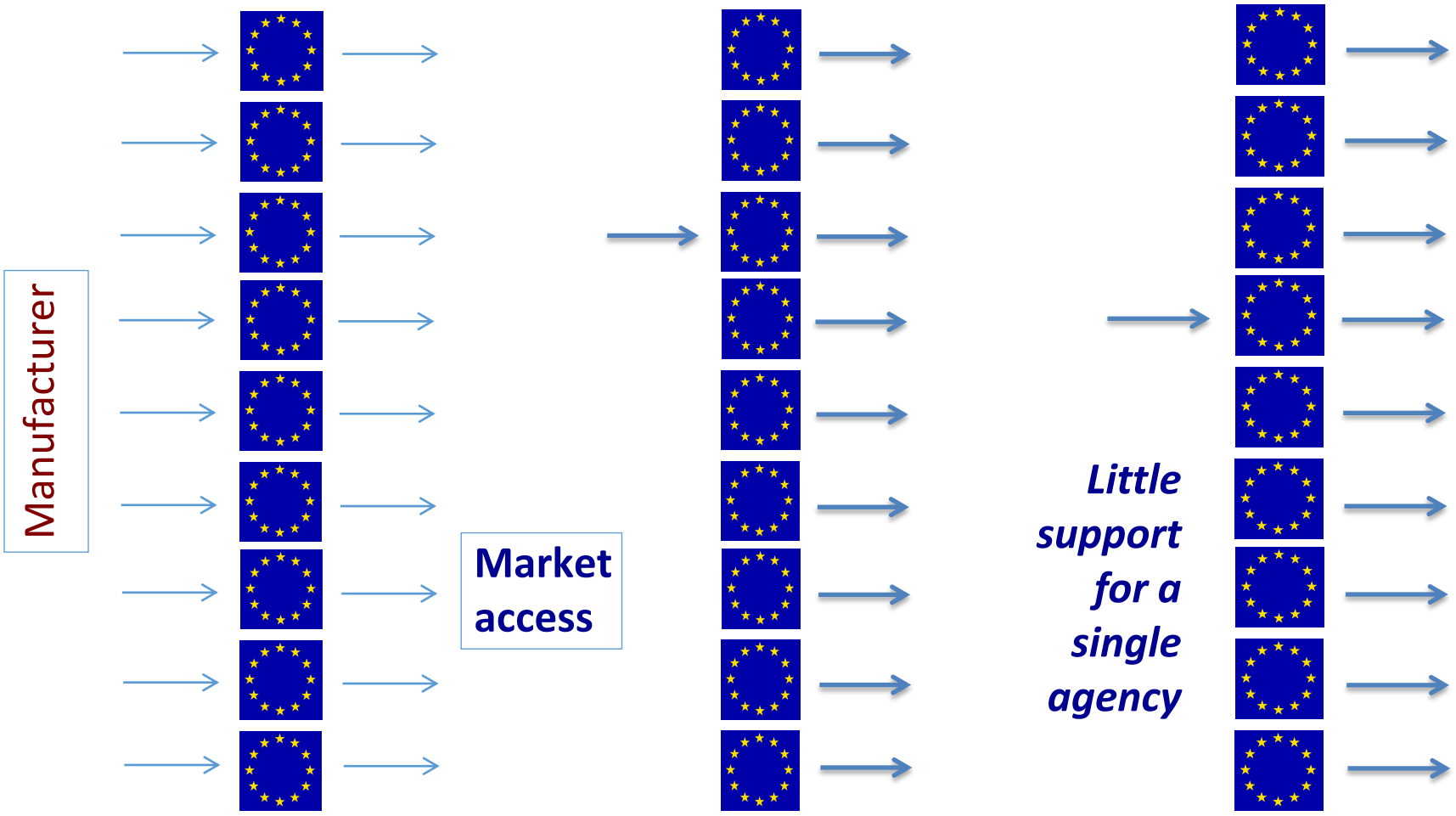
EU Pharmaceuticals

EU Medical Devices

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Before 1995

Since 1990s



Freedom of information in the European Union

Regulation EC 1049/2001 on public access to documents

- Wider access should be granted to documents in cases where the institutions are acting in their legislative capacity, including under delegated powers .. **documents should be made directly accessible to the greatest possible extent**.
- .. **all agencies** established by the institutions should apply the principles laid down in this Regulation
- In principle, **all documents** of the institutions should be accessible to the public.

http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex:32001R1049

European Medicines Agency
Pharmaceutical Products

EU **Clinical Trials Database** (EudraCT)
www.eudract.ema.europa.eu

Clinical data published at EMA website
www.clinicaldata.ema.europa.eu

- Summary of product characteristics
- **European public assessment report** (EPAR)
- Divergent expert opinion
- Committee for Medicinal Products for Human Use (CHMP) summary of opinion
- Conditions of the marketing authorisation
- EPAR Summary for the public
- Summary of risk management plan (RMP)
- Procedural steps taken and scientific information after the authorisation
- Periodic safety update reports (PSUR)

www.ema.europa.eu/ema/

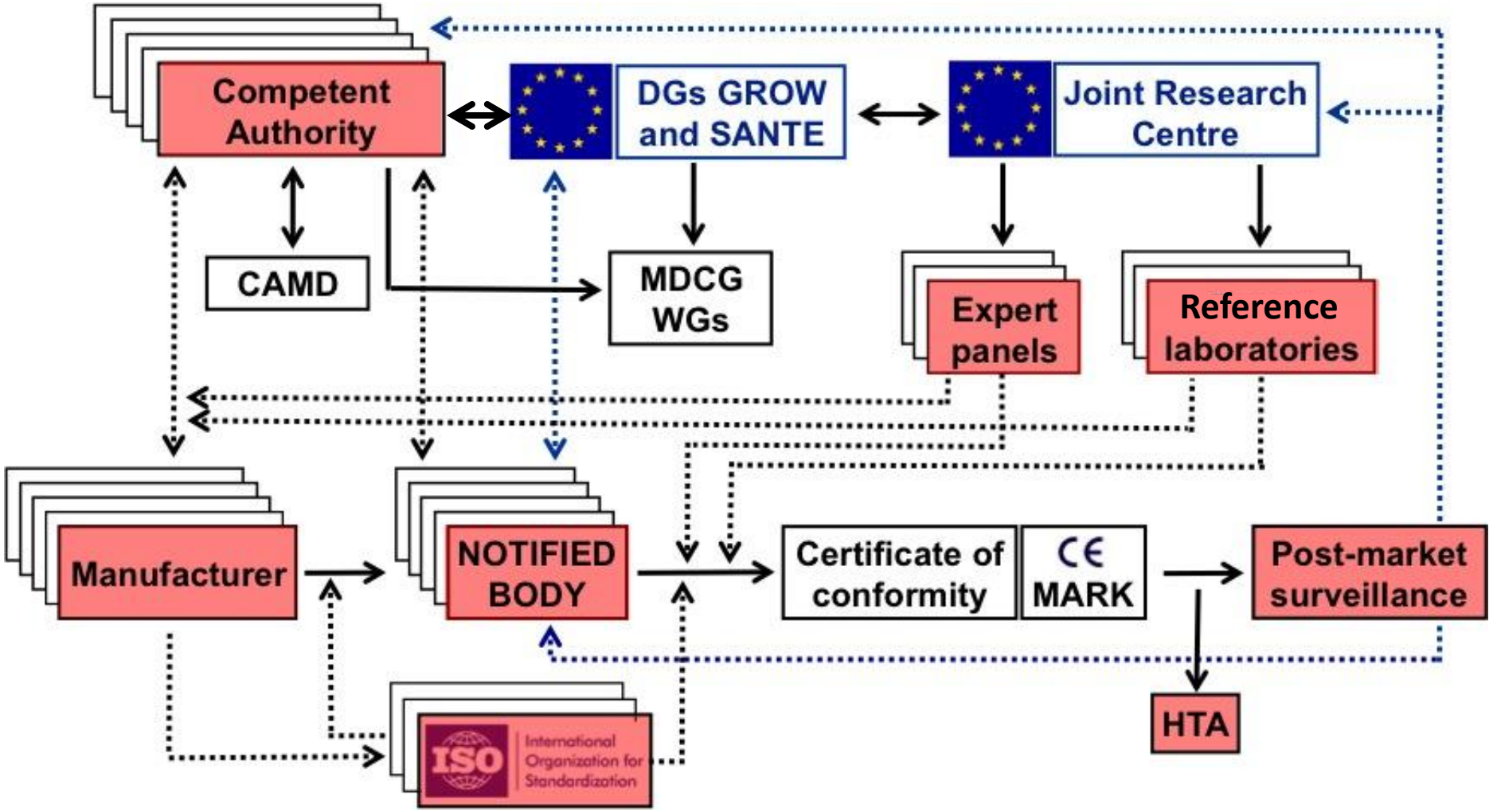
CDRH, FDA
Medical Devices

Links to relevant **trials**, all registered at
www.clinicaltrials.gov

- Definition & classification of the device
- List of devices with same product code
- **Summary of safety and effectiveness data** (SSED), including preclinical tests, relevant standards, and clinical studies
- Labeling information including instructions for use (IFU)
- Response to Premarket approval application (PMA), including instructions for conducting post-approval studies
- Record of all supplementary approvals
- Medical device recall
- Post-approval studies progress report
- **Postmarket surveillance database**

www.accessdata.fda.gov/

A complex new structure with many new tasks – but with limited capacity to implement changes



CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

CDRH Scientific & Technical Staff (January 2017 Estimates)	
Positions	**Staff Count**
Total	**1,184**
Medical, Hospital, Dental, and Public Health Group	424
Engineering Group	405
Biological Sciences Group	177
Physical Sciences Group	95
Mathematical Sciences Group	75
Veterinary Medical Science Group	8

1700 full time equivalents

Medical, Hospital, Dental, and Public Health Group	**424**
Consumer Safety Officer	132
Medical Officer	117
Regulatory Health	80
Public Health Advisor	36
Medical Technologist	26
Nurse Consultant	24
Optometrist	3
Dental Officer	3
Audiologist	2
Pharmacist	1
Veterinary Medical Science Group	
Veterinary Medical Officer	8

Courtesy Dr Jeffrey Shuren

USA 326 M / EU 508 M (2016)

Device-Specific Guidance – Expert engagement by ESC

EU Commission / Clinical Investigation and Evaluation WG

MEDDEV 2.7/1, revision 4, recommendations for clinical evidence

Coronary stents, and bioresorbable scaffolds

– systematic reviews, meta-analyses

EU Commission / Vigilance WG

Criteria for surveillance of electrophysiological ablation catheters

Criteria for surveillance of cardiac implantable electronic devices

European Network for Health Technology Assessment (EUnetHTA)

Relative effectiveness assessment (REA) of wearable cardioverter defibrillator

REA of TAVR in patients at intermediate surgical risk

International Standardization Organisation (ISO)

Review of ISO 14155, principles clinical evaluation medical devices

Revision ISO 5840 1-2-3; new ISO 5910; valve prostheses, procedures

The EU relies on international advisory standards – but it does not pay sufficiently for participation

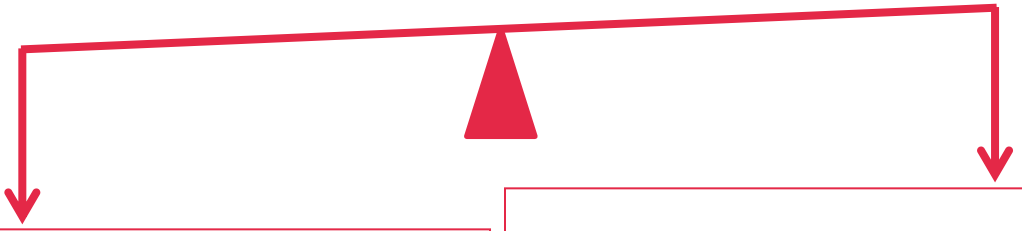
ISO International Organization for Standardization

IEC International Electrotechnical Commission

CEN European Committee for Standardization

CENELEC European Committee for Electrotechnical Standardization

INNOVATION *versus* REGULATION ?



Earlier access

Greater choice

Less evidence

Greater exposure to risks

Expanded use before proof

Delayed access

Restricted range

Efficacy established

Unexpected risks avoided

More evidence-based practice

Medical devices – ethical reasons for international collaboration in device standards and evaluation

- **Innovative high-risk / implantable devices for unmet medical needs may always carry some unpredictable risks**
- **All patients deserve equally safe medical devices**
- **Development risks should be shared equally**
- **Studies in less strict regulatory environments are unethical**

Fraser AG et al, BMJ 2011; 342: d2952

World Health Organization

67th World Health Assembly 2014
Resolution 67.20

IMDRF
International Medical Device Regulators Forum

Strategic Plan 2020

Some lessons learned ?

ESC
European Society of Cardiology

Challenges for regulators

- ✧ capacity, expertise, personnel, resources
- ✧ Integration, collaboration, transparency

Challenges for health care professionals

- ✧ research & evidence-based practice
- ✧ device-specific guidance & scrutiny
- ✧ post-market surveillance