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

Alan G Fraser
Chairman, EU Regulatory Affairs Committee

fraserag@cf.ac.uk

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The 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 advocacy on medical devices

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  The Treaty of Lisbon
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.”
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
ESC proposal for the recast

Device manufacturer → Coordinated structure applying common standards → Single unified European regulatory agency

Post-marketing surveillance → Health technology assessment → Modified CE Mark → Market authorisation

Policy conference, 28th January 2011
Clinical evaluation of cardiovascular devices
EU Pharmaceuticals

Before 1995

Manufacturer

→ Market access

EU Medical Devices

Since 1990s

Little support for a single agency
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.

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.
### CDRH Scientific & Technical Staff
(January 2017 Estimates)

<table>
<thead>
<tr>
<th>Positions</th>
<th>Staff Count</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Total</strong></td>
<td><strong>1,184</strong></td>
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<tr>
<td>Medical, Hospital, Dental, and Public Health Group</td>
<td>424</td>
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<tr>
<td>Engineering Group</td>
<td>405</td>
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<tr>
<td>Biological Sciences Group</td>
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<td>Physical Sciences Group</td>
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<td>Mathematical Sciences Group</td>
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<td>Veterinary Medical Science Group</td>
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<tr>
<td><strong>Consumer Safety Officer</strong></td>
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<tr>
<td><strong>Medical Officer</strong></td>
<td>117</td>
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<td><strong>Regulatory Health</strong></td>
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<td><strong>Public Health Advisor</strong></td>
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<td><strong>Medical Technologist</strong></td>
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<td><strong>Nurse Consultant</strong></td>
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<td><strong>Optometrist</strong></td>
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<td><strong>Audiologist</strong></td>
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<td><strong>Pharmacist</strong></td>
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<tr>
<td><strong>Veterinary Medical Science Group</strong></td>
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<tr>
<td><strong>Veterinary Medical Officer</strong></td>
<td>8</td>
</tr>
</tbody>
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*1700 full time equivalents*

*Courtesy Dr Jeffrey Shuren*
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
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*
Some lessons learned?

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