The regulation of medical devices in Europe

Role of Standards

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Design, trials, manufacturing

Surveillance audits, Regulatory requests

Regulatory approval CE Mark

Market feedback: vigilance and surveillance

Market approval / Market access
Medical devices are not what they were 50 years ago

Development of medical devices really started in the second half of the 20th century. The development of polymers, electronic engineering, and computer technology contributed to this.

Medical devices grew more sophisticated and complex.
History of regulations in the EU

**National developments** starting mid 70s

- Focused on product registration
- No attention to manufacturing process or clinical integrity
- Heavily based on pharma regulations

Resulting in high degree of *divergence*

- Different types of data required
- Different application dossier format
- Different testing requirements
- Approval times varied from a few months to 5 years

**Barrier to trade**
Need for a different approach

• More products needing legislation
• Fast technological developments and political drive to give patients access to technology quicker
• Prescriptive legislation unmanageable
EU: New Approach

- 1985 adoption of the ‘New Approach to Technical Harmonization and Standards’ by the European Council
- ‘Blue guide’: Guide to the implementation of directives based on the New Approach and the Global Approach
General principles of New Approach

• New Approach defines how directives for a specific product or product group need to be written, what elements it needs to contain
• Specific directives per product group in compliance with New Approach requirements (e.g. Electromagnetic compliance, measuring instruments, personal protective equipment, machinery, cosmetics, medical device)
Principles of New Approach

• Mandatory Essential Requirements
  – Annex I
  – Sometimes referred to as Essential Safety Requirements or Essential Health and Safety Requirements

• **Use of Harmonized standards**

• Conformity Assessment procedures involving Notified Bodies

• Manufacturer’s obligations

• National Competent Authority obligations
Directives for medical technology

MDD : 93/42/EEC
AIMD : 90/385/EEC
IVD : 98/79/EC
Machinery Directive 98/37/EC
Evolution of med dev regulation

- National legislations
- 93/42/EEC (MDD)
- 2007/47/EC (Amending directive)
- Regulation COM(2012) 542

1980’s
1993
1996
2010
2015?
Anticipated changes with the revision COM(2012) 542
Regulation, no longer a directive

Scope extension: Non-viable human tissue or cells / implantables for aesthetic purposes

Roles of the Economic Operators (manufacturer, importer, distributor, authorised representative) defined

Distributor: verifying labels (local language), CE mark, power not to distribute, role in post-market vigilance actions (work with competent authority), complaint reporting, traceability

Notified bodies: Joint assessment by NCA’s / can do unannounced factory inspections
“Qualified Person”, also at authorised representative level

Reprocessing of a single use device = manufacturing

UDI and traceability, registration of devices: ref to standards (to be developed)

Central EU database for manufacturers and EC Reps

High risk devices: public disclosure of safety data (transparency)

More demands on clinical evaluation and investigation

Portal for vigilance and market surveillance

Role of standardization is confirmed
Thank You.

The regulation of medical devices in Europe
Role of Standards

Mireille De Cré
Standards in Medical Device Compliance

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What is a standard?

‘standard’ means a technical specification, adopted by a recognised standardisation body, for repeated or continuous application, with which compliance is not compulsory, and which is one of the following:

(a) ‘international standard’ means a standard adopted by an international standardisation body;
(b) ‘European standard’ means a standard adopted by a European standardisation organisation; [ESO]
(c) ‘harmonised standard’ means a European standard adopted on the basis of a request made by the Commission for the application of Union harmonisation legislation;
(d) ‘national standard’ means a standard adopted by a national standardisation body;

Regulation (EU) No 1025/2012, OJEU L 316 14 November 2012
What is a harmonized standard?

• A standard developed under the mandate of the EU Commission by one of the recognized ESOs: CEN, CENELEC or ETSI

• The reference of the standard and its related Directive is published in the Official Journal (‘C’ Series) of the EU

• Annex ‘Z’ of the standard details the Essential Requirement(s) of the Directive that are covered
To legally apply a CE mark and place a MD on the EU market it is necessary to meet the legislation NOT the standard. (Although standards provides a vehicle to meet the legislation)
Types of standards

- **Horizontal standards** address broad aspects, common to all medical devices
  - Quality systems
  - Risk management
  - Labeling and symbols
  - Clinical evaluation

- **Semi-horizontal standards** address a set of requirements common to a group of devices
  - Sterilization
  - Biocompatibility
  - Small bore connectors for liquids and gases

- **Vertical standards** give detailed requirements for a specific device type
  - EN 455 series on medical gloves for single use
  - EN 794 series on lung ventilators
  - EN 60601 series on electrical medical devices
ANNEX Z

Medical devices — Quality management systems — Requirements for regulatory purposes

Legislation

Standard
Standards you may see:

- EN ISO 13485:2012 Quality Systems
- EN ISO 14971:2012 Risk management
- EN ISO 15223-1 Symbols
- EN ISO 14155:2011 Clinical Investigation
- EN ISO 10993-X Biological Compatibility
Why to be involved in standardization?

**Regulatory Reasons**
- Presumption of Conformity: facilitate the CE marking process
- Notified Bodies prefer transparent policies on how manufacturers keep in touch with standard changes

**Market Access Reasons**
- Tenders request compliance with standards
- Health Insurance/ National health reimbursement to be linked to meeting state of the art requirements in standards
- Influencing the standards development process: be pro-active!
Standards Development in Europe

International Level

ISO  International Organization for Standardization
IEC
ITU  International Telecommunication Union

EU Level

CEN
CENELEC
ETSI  World Class Standards

National Level

AENOR
DIN
NEN
UN
BSI
DS
NSAI
et al...
Standards Development in Europe

- Vienna Agreement
- Dresden Agreement

ISO
International Organization for Standardization

IEC

CEN

CECELEC
Standards Development

Who writes standards?

You
Thank You.

Standards in Medical Device Compliance

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