EHR in the Healthcare sector

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LÄKEMEDELSVERKET
MEDICAL PRODUCTS AGENCY

Agenda

- **New approach in EU**
- **CE marking of MD**
- **Responsibilities**
- **Regulations and requirements**
- **Problems and improvement areas**
- **Reccomendations**

The *NEW APPROACH*

The regulatory technique are described in the Blue Guide.

The *NEW APPROACH*

This regulatory technique established the following principles

- Legislative harmonisation should be limited to the **essential requirements** (preferably performance or functional requirements) that products placed on the EU market must meet if they are to benefit from free movement within the EU
- The technical specifications for products meeting the essential requirements set out in legislation should be laid down in **harmonised standards** which can be applied alongside the legislation.

The *NEW APPROACH*

This regulatory technique established the following principles

- Products manufactured in compliance with harmonised standards benefit from a **presumption of conformity** with the corresponding essential requirements of the applicable legislation…
- The application of harmonised or other standards **remains voluntary**…
- The manufacturer may be required to submit the product to a ***Notified Body*** to have the conformity assessment carried out…

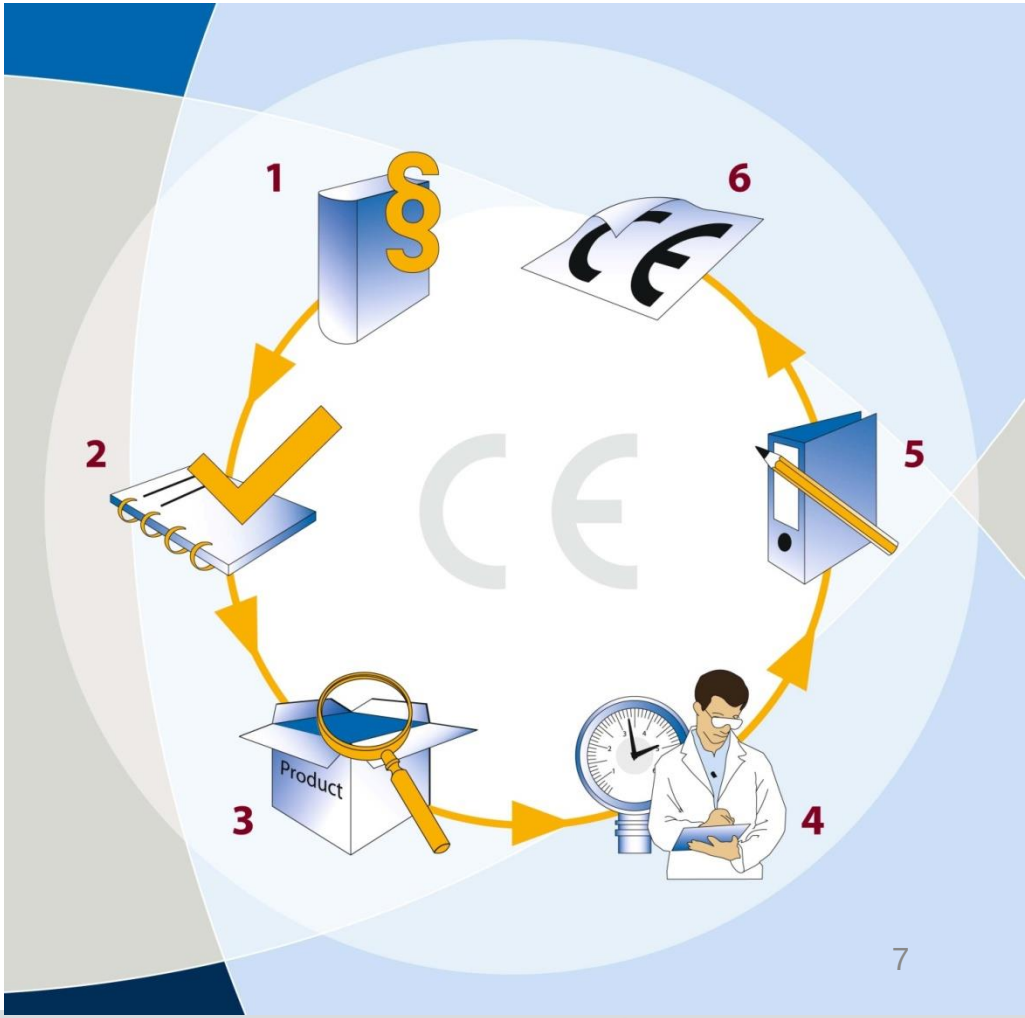
Obligations for manufacturers

1. The manufacturer is any natural or legal person who manufactures a product or has a product designed or manufactured, and places it on the market under his own name or trademark.
2. The manufacturer is responsible for the conformity assessment of the product and is subject to a series of obligations including traceability requirements.
3. When placing a product on the Union market, the responsibilities of a manufacturer are the same whether he is established outside the European Union or in a Member State.
4. The manufacturer must cooperate with the competent national authorities in charge of market surveillance in case of a product presenting a risk or being non-compliant.

6 steps to CE marking your product

1. **Identify directives**

- **AIMD 90/385/EEC**
- **MDD 93/42/EEC**
- **IVD 98/79/EC**



6 steps to CE marking your product

2. **Verify requirements**

6 steps to CE marking your product

3. **Need for notified body?**

6 steps to CE marking your product

4. **Check conformity**

6 steps to CE marking your product

5. **Technical documentation**

6 steps to CE marking your product

6. **Affix CE marking**

COUNCIL DIRECTIVE 93/42/EEC

14 June 1993 concerning medical devices

Medical device means any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of:

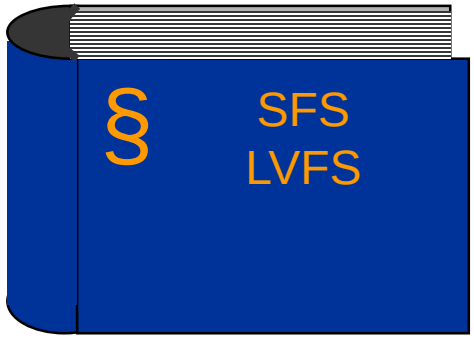
- diagnosis, prevention, monitoring, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,
- investigation, replacement or modification of the anatomy or of a physiological process,
- control of conception

COUNCIL DIRECTIVE 93/42/EEC

14 June 1993 concerning medical devices

… and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means

Swedish implementation



- **Medical Devices Act (SFS 1993:584)**
  - Medical Products Agency´s regulations:
  - LVFS 2001:5 on AIMD
  - LVFS 2003:11 on MDD
  - LVFS 2001:7 on IVD

  and
  - LVFS 2014:7 on NMI

Medical Devices in Sweden

Regulations for & control and supervision of
- Medical **device**s placed on the market
- **Manufacturers** placing products on the market

www.lakemedelsverket.se

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Regulations for
- **the usage** of medical devices in health care
- **own production** of medical devices in health care

http://www.socialstyrelsen.se

Socialstyrelsen

Control and supervision of
- **the usage** of medical devices in health care
- **own production** of medical devices in health care

http://www.ivo.se

Inspektionen för vård och omsorg

Essential requirements

I. GENERAL REQUIREMENTS

1. The devices must be designed and manufactured in such a way that, when used under the conditions and for the purposes intended, they will not compromise the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons, provided that any risks which may be associated with their intended use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety.

This shall include:

- reducing, as far as possible, the risk of use error due to the ergonomic features of the device and the environment in which the device is intended to be used (design for patient safety), and
- consideration of the technical knowledge, experience, education and training and where applicable the medical and physical conditions of intended users (design for lay, professional, disabled or other users).

Regulation

- The product shall have the adequate features that support the intended purpose
- Patient safety shall be considered in the risk management process
- The manufacturer shall demonstrate that the performance of the product really meets the intended purpose
- The manufacturer must verify that the software fulfils the essential requirements as specified in annex 1 in the Medical Product Agency's regulation (LVFS 2003:11) (annex 1 in Directive 93/42/EEC on medical devices). The risk management process shall include evaluation and justification of risk level for a product, and also control the selection of verification methods against defined acceptance criteria.

Regulation

- The functionality and usability of the product must be validated and, when applicable, also be clinically evaluated.
- Both the product's software and specified hardware must be safe in single fault condition.
- The documentation shall contain all information necessary to be able to use the product in a safe and proper way.
- The documentation must be in Swedish and adapted for the intended user. This applies both for user instructions as for user interface.
- The user documentation shall also include the necessary technical information for maintenance, installation and administration. This involves managing ”unreliable” components: SOUP, internet, network, power and servers shall be described.

Regulation

Controlled processes for device design

Apply relevant standars:

- ISO 13485, Medical devices – Quality management systems – Requirements for regulatory purposes.
- IEC 62304 describing a structured development process for medical device software.
- ISO 14971 for risk management.
- ISO 80001-1 describes a controlled and standardised method for verifying installation work in a user’s network

Regulation

- The clinical evaluation is described in annex 10 in the Medical Product Agency's regulation (LVFS 2003:11) (annex 10 in Directive 93/42/EEC on medical devices). All process documentation are parts of the product's technical file.

Regulation

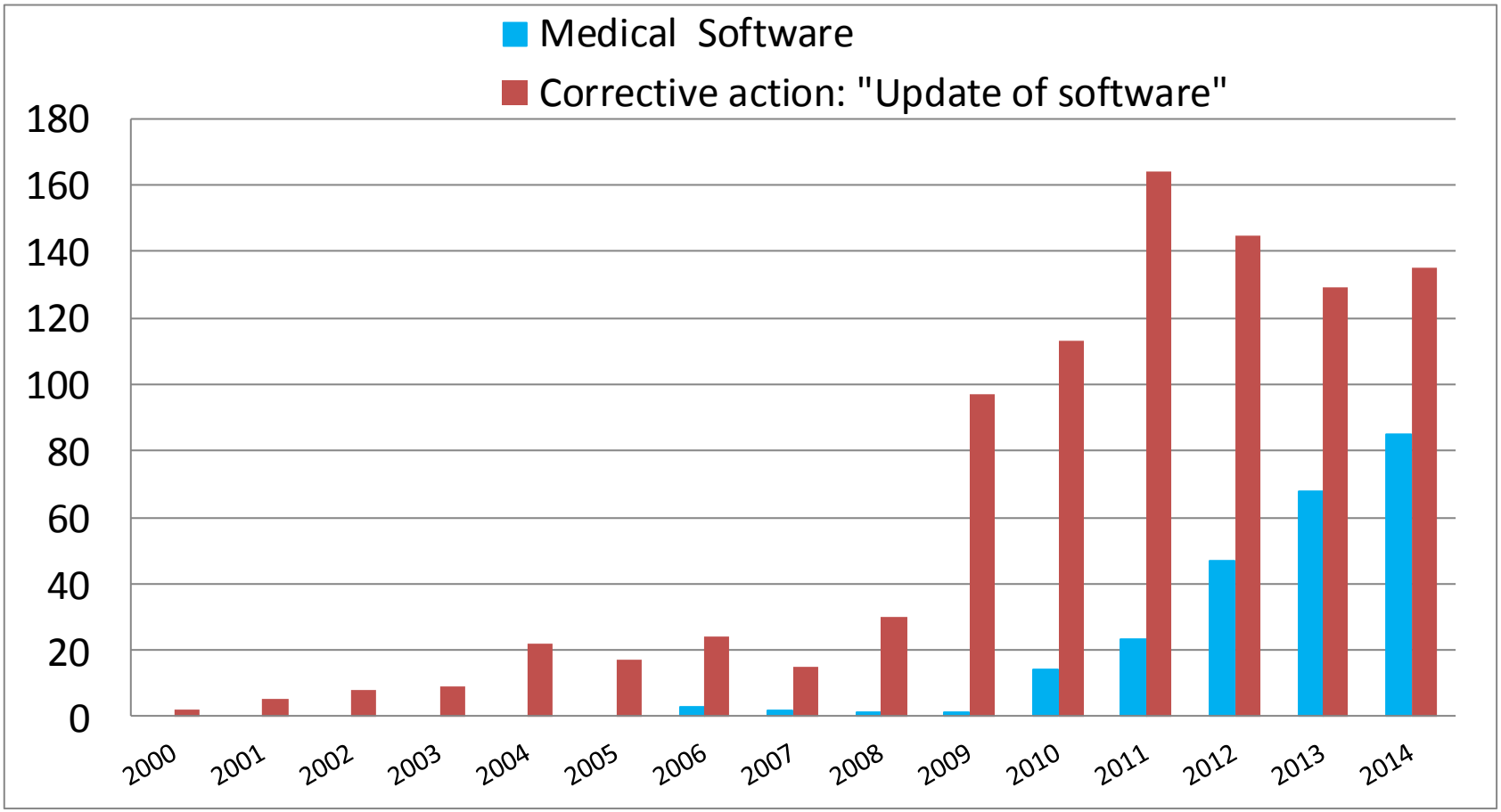
- The manufacturer is responsible for actively following up experiences from the practical use of the system.
- In that respect, the manufacturer ”owns” the system's risk analysis and is the one that shall take decisions on e.g. changes of functionality or safety measures in the system.
- Complaints handling should include risk assessment and communication with customers. The vigilance process shall include reporting of accidents and near-accidents

Market control by MPA

- Surveillance of manufacturers and distributors of medical devices
- If hazardous or defective devices are discovered, MPA can issue an injunction ordering a manufacturer, or other person, to provide warning information for the devices in question
- Medical Products Agency may also prohibit or restrict the sale of such devices or demand that a problem is rectified or that a product is recalled.
- If a manufacturer is issued with an injunction to modify a device, this can mean that no more devices of that model may be sold until the problem is rectified, or that the device must be recalled for rectification.
- Medical Products Agency can combine injunctions and prohibitions with contingent fines or sentence to imprisonment for a maximum of one year.

Accidents and near-accidents

Reported incidents and field safety correcitve acctions



Medical Information Systems

- wrong patient id
- mixed data from more than one patient
- wrong ordination of medicine – type/strength/number
- wrong start or stop of medication
- switch of patient between registration and expedition of ePrescription
- “wrong” sort order: 10,100,20,30
- Errors from special characters (å,ä,ö, ½, >,<, %...)

Improvement areas

EHR/Patient record systems/PACS/RIS …

- Compatibility/interoperability – reduce number of communication protocols
- Increased requirements for test of code and functions, validation of new software interacting with old and/or third party software
- Clinical evaluation / Intended use
- Health care providers should require and buy CE marked, compatible systems
- Manufacturers should register at MPA (Class I) or engage Notified Body (Class IIa)
- Manufacturers must learn requirements and deliver correctly CE marked products

Recommendations

- Adhere to rules and directives: MDD, LVFS
- Use guidelinse: LV, MEDDEV, FDA, IMDRF
- Use harmonised standars:
  - ISO 13485, 14971
  - IEC 62304, 62366
- Ask MPA-MD
- Engage consultants (Swedish Medtech)
- Engage Notified Body


Thanks