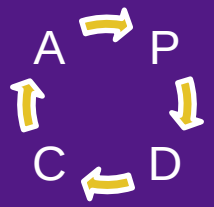
RECALLS in EUROPE

Past, present, near & further future



Gert Bos – BSI – Medcon May 2012

Content

- Current positioning of recalls in EU system
- Examples of current debate
- What the PIP….
- Interim Measures 2012
- Future legislation and recalls
- discussion

Recall in current legal framework

- Directives cover manufacturer to send recall information from their PMS system to Authorities

- Guidelines cover the activities of all stakeholders:
  - Commission,
  - Competent Authorities,
  - Manufacturers (including authorized representatives and persons responsible for placing on market)
  - Users and others concerned with continuing safety of medical devices

QMS

PMS

Vigilance

Reactive PMS

Proactive PMS

Post Market Clinical Follow-up

Reactive:

Might lead to RECALL

- detection of manufacturing problems.
- service records.
- compatibility with other devices.
- device misuse.
- customer satisfaction.
- continuing market viability.

Might lead to RECALL

Reactive:

Might lead to RECALL

- vigilance.

Might lead to RECALL

Proactive:

Might lead to RECALL

- focus groups.
- customer surveys.
- user feedback via training programs.
- implant registries.
- other bodies (eg. CA).
- media.
- experience with similar devices.
- retrieval studies.

Might lead to RECALL

Proactive:

Might lead to RECALL

- Post market clinical follow-up.

Might lead to RECALL

Risk Management

Risk analysis

- Intended use/intended purpose identification of characteristics related to the safety of the medical device
- Identification of hazards
- Estimation of the risks for each hazardous situation

Risk evaluation

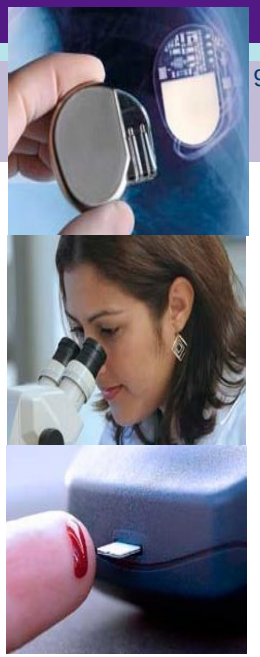
Risk control

- Risk control option analysis
- Implementation of risk control measure(s)
- Residual risk evaluation
- Risk/benefit analysis
- Risks arising from risk control measures
- Completeness of risk control

Evaluation of overall residual risk acceptability

Risk management report

Production & post production information



Essential in determining and follow up of RECALL

Recall embedded in risk management

- Acceptability of the risk
- Causality, probability & actions to prevent reoccurrence
- Severity and recognisability of the failure,
- Requirements of Harmonised Standards
- Essential requirements according to Directives
- Need of corrective action and precautionary measures
- Suitability of proposed or taken measures by the manufacturer

Safeguard clause

- Where a Member State ascertains that the devices when correctly installed, maintained and used for their intended purpose, may compromise the health and/or safety of patients, users or, where applicable, other persons, it shall take all appropriate interim measures to withdraw such devices from the market or prohibit or restrict their being placed on the market or put into service.

=> Hardly ever used – complex procedures

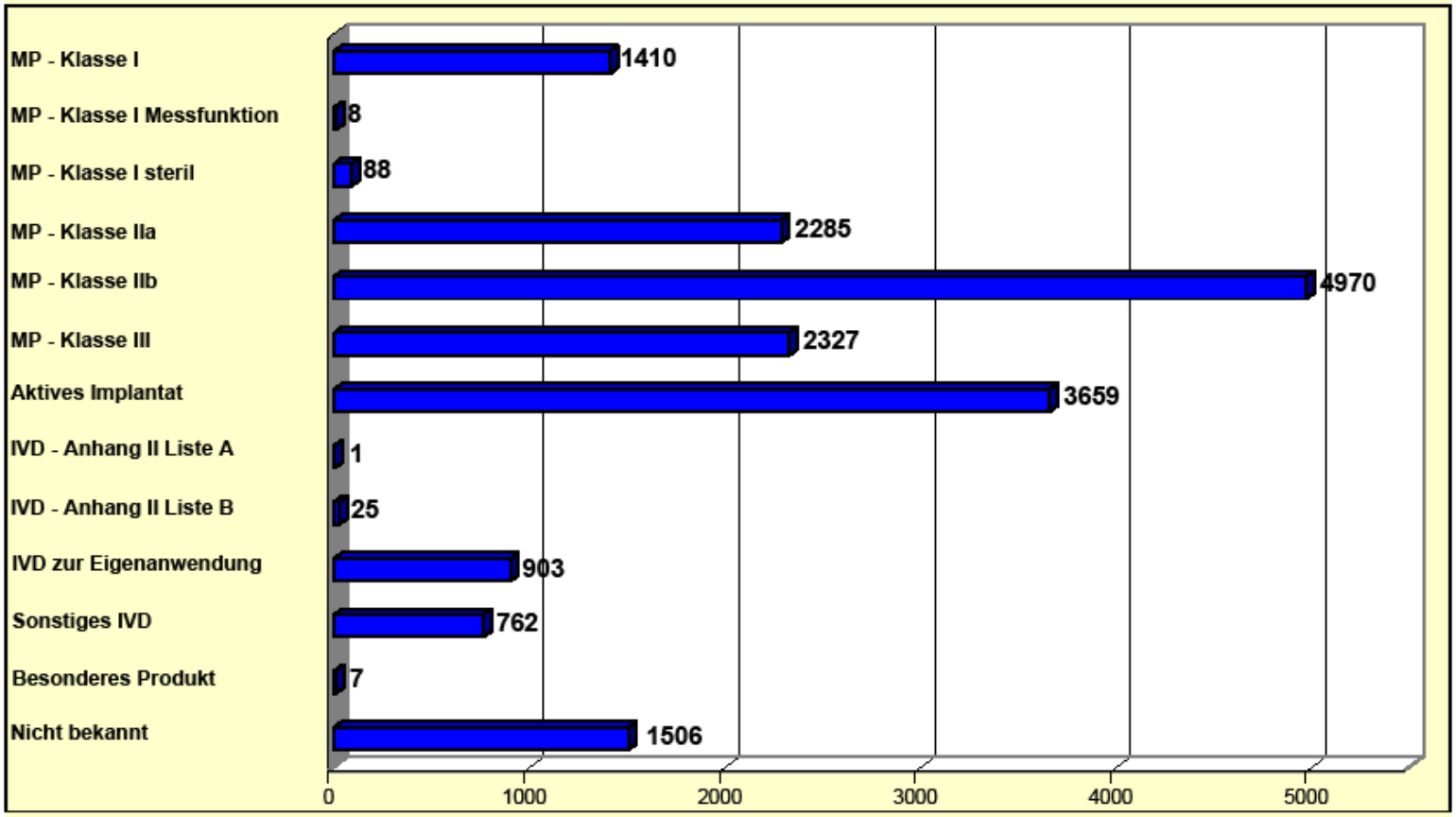
=> Voluntary recall instead

=> Agreement between manufacturer and country

Risks/reports according to risk classes

Statistische Auswertung der im Zeitraum 01.01.2005 bis 31.12.2009 abschließend bewerteten Risikomeldungen

Verteilung nach Risikoklassen



Stand 22.02.2010
Anzahl der auswertbaren Risikomeldungen: 17951
Bundesinstitut für Arzneimittel und Medizinprodukte

BfArM

Courtesy Roger Grase

· PARTNERSHIP

BSI

EU recent updated guidance

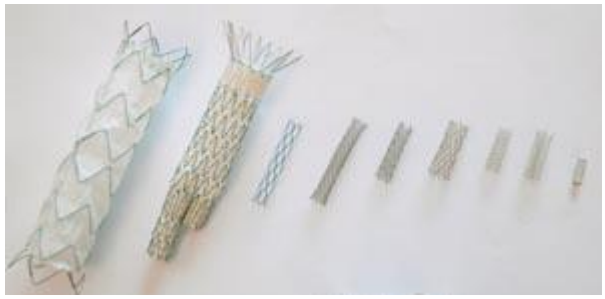
- MEDDEV Vigilance system (2.12-1 rev.7)
  - Manufacturers Incident Report Form
  - FSCA
  - Manufacturers Trend reporting form
  - Manufacturers Periodic Summary Reporting form

=>FSCA defines as synonym for recall

  - Manufacturers to report to Authorities
  - Authorities to review and supervise
  - Notified Bodies to review process and impact of FSCA
  - Commission to look for coordination and cooperation

Recalls – current situation

- Most recalls initiated from manufacturers
- Medical device recall: a different image



⇔

Recall data on Authorities Alertpages

MHRA

Healthcare professionals | Patients and public | Pharmaceutical industry | Devices industry

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In Publications and consultations

- Safety warnings
  - Drug Alerts
  - Medical Device Alerts
- Safety guidance
- Regulatory guidance
- Consultations
- Public Assessment Reports
- Corporate
- Consumer
- Posters and leaflets

Section search

Home › Publications and consultations › Safety warnings › Medical Device Alerts

Monthly list of MDAs 2012

Medical Device Alerts issued in March 2012:

MDA/2012/009 Level 1® Normothermic IV fluid administration sets, specific lots of model numbers D-60 HL and DI-60HL. Hotline® Blood and IV fluid warming sets, specific lots of model numbers L-70, L-70NI, L-80, L-270, and L-370. Manufactured by Smiths Medical. 01/03/2012

MDA/2012/010 AlboGraft Polyester Vascular Graft: manufactured by LeMaitre. All Lots. 07/03/2012

MDA/2012/011 Silicone gel filled breast implants manufactured by Poly Implant Prothese (PIP). All implanted devices. 15/03/2012

MDA/2012/012 Patient vital signs monitor. IntelliVue models MP20, MP30, MP40, MP50, MP60, MP70, MP80, MP90, D80, MX600, MX700, MX800.Manufactured by Philips Healthcare.Affected software revision H up to and including H.15.36. 15/03/2012

MDA/2012/013 Electrosurgery instrument. LigaSure Dolphin Tip sealer/divider LS1500 and LS1520 manufactured by Covidien. Specific lot numbers. 15/03/2012

MDA/2012/014 Implantable cardioverter defibrillators (ICD). EnTrust VR/DR/AT. Models: D153ATG, D153DRG, D153VRC, D154ATG, D154DRG, and D154VRC.Manufactured by Medtronic. 16/03/2012

MDA/2012/015 Sterile indigo carmin manufactured by Derm Tech. 29/03/2012

Printer friendly version (new window)

Document details:

Type:	Medical Device Alert
Series No:	n/a
Audience:	Healthcare professionals
Published:	
Format:	Electronic only
Size:	A4
Pages:	3
Price:	Free
ISBN/ISSN:	n/a
Author:	
Copyright:	Crown

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BSI

Recalls in the EU media

- Alert systems MHRA (UK), AFSAPPS (France), etc.
- No overview, no detailed analysis
- In the news:
  - Breast implants (PIP and M-implants)
  - Metal on Metal hip implants
  - Pacemaker leads
  - Soft tissue reconstructive meshes

The following section/document has been added/updated

Title:

Medical Device Alert: Left ventricular cardiac resynchronization therapy (CRT) leads manufactured by St Jude Medical (MDA/2012/021)

Summary

This Medical Device Alert has been issued as there is a risk of worsening heart failure symptoms due to wear and/or abrasion of lead insulation after implantation.

Conclusion CURRENT recall practice

- Completely controlled by Manufacturers
- ‘dear doctor’ letters and advisory notices
- Depending on situation reporting to Authorities under vigilance system, including details of recall action
- Review vigilance cases and recalls during Notified Body audits – sampling from overview
- Review vigilance reports by some
- Only active element is from manufacturer
- Improvement is essential

What the PIP…….

- PIP is a case of well engineered FRAUD
- Public image of sector is challenged
- European Parliament critical questions
- Commissioner Dalli speeching, wrote to MoHs & addressed Manufacturers and Notified Bodies
  - Short term changes demanded
  - Authorities Report to Parliament before summer break
- Legislative changes delayed with months or more
- Reflections on system, not on product type

Interim measures - selection

- Specific list of items to be verified by Notified Body during audits
- Contracts to send all vigilance reports to Notified Body, and NBs to get access to EUDAMED
- Competent Authorities to boost resourcing on market surveillance
- Coordinated analysis of vigilance reports, and coordinated audits of manufacturers and importers
- Use of UDI will aid in recall
- Professional and national implant registries
- System where healthcare professionals and users to report problems to authorities

FDA alerted to some older cases

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
U.S. FOOD AND DRUG ADMINISTRATION

Unsafe and Ineffective Devices Approved in the EU that were Not Approved in the US

StarTribune | business

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FDA rips Europe's system for medical device reviews

Article by: JIM SPENCER and JAMES WALSH , Star Tribune | Updated: April 22, 2012 - 9:33 AM

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RF REGULATORY FOCUS

Report: Internal FDA Reports Slams European Regulation of Medical Devices as Ineffective

Latest News | Posted: 23 April 2012

What will be in the MD and IVD Regulations?

ROADMAP			
TITLE OF THE INITIATIVE Start: 2008	**1. Proposal for a Regulation of the European Parliament and of the Council concerning medical devices and repealing Directives 90/385/EEC and 93/42/EEC;** **2. Proposal for a Regulation of the European Parliament and of the Council concerning in vitro diagnostic medical devices and repealing Directive 98/79/EC;** **3. Communication regarding the innovation in medical devices for the benefit of patients, consumers and healthcare professionals**		
TYPE OF INITIATIVE	**X** CWP act • Non-CWP • Implementing act/Delegated		
LEAD DG – RESPONSIBLE UNIT	SANCO/B2		
EXPECTED DATE OF ADOPTION	Month/Year: 2nd quarter 2012		
VERSION OF ROADMAP	No: 3	Last modification:	Month/Year: 7.11.2011

Key Elements to the Framework

Industry

Member States
- Market Surveillance
- Vigilance

Notified Bodies
- Notified Bodies
- Clinical Evaluation
- Transparency

=> All need improvement based on over a decade of experience

New MDD/AIMD - definitions

- Art 2 - 1(s) - ‘recall’ means any measure aimed at achieving the return of a device that has already been made available to the end user; [definition from Reg. 765/2008]

RECALL defined

Art 7.4 – obligation manufacturer

RECALLS registered

- Keep up to date a systematic procedure to collect and review experience gained from their devices in the post-production phase
- Implement appropriate means to apply any necessary corrective actions (post-market surveillance plan)
- May include, if deemed appropriate, sample testing of marketed products, investigation of complaints and keeping a **register of non-conforming products and product recalls or withdrawals.**

Art 7.8 – obligation manufacturer

- Manufacturers who consider or have reason to believe that a device which they have placed on the market is not in conformity with this Regulation shall immediately take the necessary corrective measures to bring that product into conformity, **to draw it or recall it**, as appropriate.

Fast actions on RECALL

9.5 / 9.6 – obligations importers

- When deemed appropriate with regard to the risks presented by a device, importers shall, to protect the health and safety of patients and users, carry out sample testing of marketed products, investigate, and, if necessary, keep a register of complaints, of non-conforming products and **product recalls**, and shall keep distributors informed of such monitoring.
- Importers who consider or have reason to believe that a device which they have placed on the market is not in conformity with this Regulation shall immediately inform the manufacturer and his authorised representative and, if appropriate, take the necessary measures to bring that device into conformity, withdraw or recall it. Furthermore, where the device presents a risk, importers shall immediately inform the competent authorities of the Member States in which they made the device available to that effect, giving details, in particular, of the non-compliance and of any corrective measures taken.

Importers to RECALL

10.4 – obligations distributors

- Distributors who consider or have reason to believe that a device which they have made available on the market is not in conformity with this Regulation shall make sure that the corrective measures necessary to bring that device into conformity are taken, withdraw it or recall it, as appropriate. Furthermore, where the device presents a risk, distributors shall immediately inform the manufacturer and, where applicable, the authorised representative and the importer, as well as the competent authorities of the Member States in which they made the device available to that effect, giving details, in particular, of the non-compliance and of any corrective measures taken.

Distributors to INFORM

51a - Procedure for dealing with non-compliant devices presenting a risk

- Competent authorities shall without delay require relevant economic operator to take all appropriate and duly justified corrective action
  - Bring device into compliance
  - Prohibit or restrict device's being made available
  - Withdraw the device from the market, or to timely recall it
- Competent authorities shall inform Commission and other Member States of results of evaluation and actions required
- Economic operators ensure appropriate corrective action
- If no timely action, competent authorities shall take all appropriate provisional measures to prohibit or restrict the device's being made available on their national market, to withdraw the device from that market or to recall it.

Authorities to RECALL

51.8 – Commission recalls

- All Member States shall ensure that appropriate restrictive measures are taken in respect of the device concerned, such as recall or withdrawal of the device from their market, without delay. Where a Member State or the Commission consider that a measure should be adopted at EU level to ensure a uniform level of protection in all Member States, the Commission, at the request of a Member State or on its own initiative, may take the necessary and duly justified measures to ensure the protection of health and safety, by means of implementing acts, taking into account the principle of proportionality. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article Y [Implementing Act].

Commission to RECALL

53 - Procedure for dealing with compliant devices which present a risk to health and safety

- Member State finds that although a device is in compliance with this Regulation, it presents a risk to the health or safety of persons or to other aspects of protection of public health
- Member State shall require the relevant economic operator(s) to take all appropriate provisional measures:
  - no longer presents that risk when placed on market
  - withdraw the device from the market
  - recall it within a reasonable period, commensurate with the nature of the risk

Authorities to RECALL

54 – Formal non-compliance

- Member State forces economic operator to end non-compliance concerned:
  - conformity marking affixed in violation of the formal requirements
  - conformity marking has not been affixed;
  - EC declaration of conformity not (correctly) drawn up or incomplete
  - IFU not available, not complete, not correct or not provided in language required
  - technical documentation, including clinical evaluation, not available, not complete or fails to duly demonstrate conformity with essential requirements
- Where above non-compliance persists, the Member State concerned shall take all appropriate measures to restrict or prohibit the product being made available on the market or ensure that it is recalled or withdrawn from the market. This Member State shall inform the Commission and the other Member States, without delay, of those measures.

Authorities to RECALL

55 - Preventive health protection measures

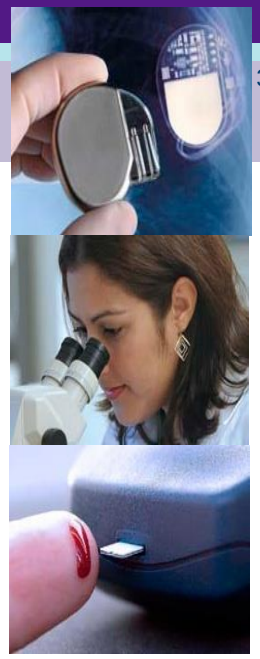
- Where Member State determines a device, specific category or group of devices should be prohibited, restricted or subjected to particular requirements or be withdrawn from the market or recalled in order to ensure protection of health and safety and/or to ensure that public health requirements are observed it may take any necessary and justified provisional measures
- Member State shall inform Commission and other Member States including the reasons
- Commission decides whether the national measures are justified or not. Commission shall inform Member States and consulted interested parties about its decision
- Where measures should be taken in all Member States in order to ensure protection of health and safety and/or to ensure that public health requirements are observed, Commission shall be empowered to take necessary and duly justified measures by means of adoption of delegated acts

Authority & Commission to RECALL

Conclusions

- Current recall system in EU based on manufacturers risk assessment
- Legal system challenged by PIP and other cases
- Legal system under revision
  - Increased transparency
  - Recall defined
  - Stakeholders responsibilities defined
  - Roles for manufacturer, importer and distributors enhanced
  - Recalls initiated also by Member States and Commission
- Interim Measures underway

The END ….



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