Life cycle approach to market surveillance of medical devices

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Introduction

• Market surveillance: current position within the EU

• Challenges

• Strengthening and reinforcing market surveillance

• Developing new approaches and methodologies

• Revision of the medical device legislation
Market Surveillance – Direct Definition

• **EU Regulation 765/2008, Art.1-17:**

‘market surveillance’ shall mean the activities carried out and measures taken by public authorities to ensure that products comply with the requirements set out in the relevant Community harmonisation legislation and do not endanger health, safety or any other aspect of public interest protection;
Market Surveillance - Indirect Definition

• **MDD 93/42/EEC, Art. 2 - Placing on the market and putting into service**

Member States **shall take all necessary steps to ensure that devices** may be placed on the market and/or put into service **only if they comply** with the requirements laid down in this Directive when duly supplied and properly installed, maintained and used in accordance with their intended purpose.
**Medical Device Life Cycle**

- Concept
- Pre-clinical
- Pre-market
- Clinical
- Manufacturing
- Commercial Use
- Marketing
- Post-market
- Decommissioning
- Prototype

**Clinical Decommissioning**

**Pre-market**
Market Surveillance: Goals

- Public health is protected effectively

- Medical devices placed on the market continuously conform to the requirements for safety and performance

- Problems or changes in safety and performance of a medical device are detected and acted on in an effective and timely manner

- Medical device market surveillance activities are effective to cover national responsibilities and provide valuable input into European system

- Data gathered from market surveillance is used to drive better standards of safety and performance - inform other phases in the lifecycle
Market Surveillance: Challenges

- Different interpretations and approaches to the activities which constitute medical device market surveillance
- Decentralised system for conformity assessment/certification and market surveillance – chain is only as strong as the weakest link
- Lack of transparency and information on products available
- Array and complexity of medical device technologies and ensuring effective regulation
- Iterative nature of medical device product development
- Learning curve associated with technology advances
Joint Plan for Immediate Actions - 2012

- Reinforce market surveillance of medical devices
- Proposed as key area for further development and coordination
- Information gathering on ongoing market surveillance activities
- Need to develop and agree commonly agreed principles and definitions for market surveillance activities
- Commission report on implementation (June 2014) – market surveillance is the key priority requiring further development and focus
Range of Approaches

- Different practice, intensity, targets, measures taken and resource levels

- Different inputs & triggers

- Different focus – some focus on products manufactured on their territory, others focus on registration of devices placed on their market

- Variance in the extent of product reviews e.g. labelling checks vs. technical file review

- Different levels of cooperation with external bodies e.g. customs

Conclusions

- Difficult to compare/measure activity levels due to differences in definitions

- Difficult to coordinate and manage activities due to differences in approach and level of information available

- MS authorities are aligned in terms of objectives and principles of market surveillance – afford effective protection of public health

- Highlights need for better information sharing and common understanding of relevant terminology
Market Surveillance: Bringing about change

- Considerable discussion at EU level on changing the focus and direction

- Need to use all available device information and data sources as foundation for market surveillance activity

- Need to develop and ensure the capability of information and data sources

- Need to ensure cooperation, coordination and optimal utilisation of resource for surveillance activities in EU

- Need to increase harmonisation in approach and predictability of outcome
Change in approach

Lifecycle Market Surveillance

An approach to market surveillance which involves using data and information from all stages of the lifecycle of a medical device to direct and support the conduct of surveillance activities and investigations. The outcome and findings from these post-market investigations are used to update, develop and reinforce new pre-market requirements.
Current considerations – improving cooperation and coordination

- Communication and coordination between MS authorities
- Communication, coordination, and cross-working between European working groups involved in market surveillance
- Need for overseeing policy development for market surveillance
- Conducting joint enforcement activities; exchange of officials
- Increasing support for technical working groups
Current considerations – harmonisation of approach 1

- Developing a common approach to risk assessment and prioritisation of products subject to market surveillance

- Ensuring high risk and innovative products are subject to effective levels of market surveillance e.g. post-market clinical follow up

- Developing key performance benchmarks and peer review schemes for market surveillance

- Promoting the implementation of common guidelines and agreements in member states

- Effective and appropriate levels of market surveillance for devices developed in professional use setting e.g. custom made devices
Current considerations – harmonisation of approach 2

Imports into the Union

- Mapping the differences in dealing with safety and compliance controls for products entering the Union
- Development of a common risk based approach to customs product safety and compliance controls

Sales on-line

- Developing methodologies to monitor and address non-compliant products sold on line
Current considerations

Developing Engagement

- Increasing strategic involvement of the Commission and its institutions e.g. JRC
- Active involvement of European organisations representing patients, HCPs, manufacturers, SMEs and others

Information and Data Sources

- Maximise benefits of IT systems
- Create synergies between IT systems – national/EU systems, RAPEX
- Improve product traceability
Lifecycle Market Surveillance

- Pre-clinical/technical
- Clinical studies
- Conformity assessment/certification
- Clinical evaluation
- Clinical use
- PMS/PMCF
- Vigilance/Market surveillance
- Risk analysis
- Risk metrics
  - FSCA
- Registers
  - PMCF study reports
- FSCA Signals
- Clinical risks/hazards
- Feedback
  - Unidentified risks
  - Use issues
  - Suitability of measures
- Risk metrics
  - FSCA
HPRA Developments: 2013 Review of Medical Device Activities 1

- Developing HPRA capability in line with joint plan and prepare for new legislative framework

- Working to strengthen, secure and build confidence in the regulatory system for medical devices at national, European and international level

- Optimising HPRA’s regulatory processes, utilisation of resources, expertise and knowledge of medical devices

- Contributing to the development of mechanisms to enhance cooperation, communication and partnership between regulatory authorities in Europe and internationally

- Working to ensure that the improved functioning of the regulatory system in Europe directly contributes to ensuring the safety and quality of devices on the Irish market
HPRA Developments: 2013 Review of Medical Device Activities

- 4 year strategy for HPRA’s medical device activities setting out 14 high level cross-organisational objectives
- Focus on developing and evolving current approaches to all medical device activities
- Further utilisation of models of risk based regulation and planning to ensure that medical device resources are optimally used
- Specific focus on reinforcing market surveillance of medical devices and adoption of an approach which covers the device lifecycle – involving each department in market surveillance
- Increasing contribution to the joint assessment process
- Further developing and enhancing vigilance functions and activities
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Pre-market evaluation
Post-market surveillance

Medial device policy

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New Regulations: new market surveillance provisions

- Enhanced provision for conformity checks – technical documentation, evaluations, physical/laboratory checks

- Activities should be based on risk assessment principles and founded on inputs from various sources vigilance, complaints, others (clinical data, PMCF etc.)

- Includes provision for systematic planning and coordination

- Exchanging information between countries, with customs/border control with third countries

- Includes provision for Implementing Act to increase definition, clarity and detail in relation to market surveillance activities for
Conclusions

- Post-market surveillance plays a key role in enhancing the safety and quality of medical devices available on the EU market

- Lack of harmonisation and inconsistencies in approach taken by member states has negatively impacted on effectiveness

- Need for reinforcement of market surveillance and change of approach identified

- Future focus: more effective use of information from all stages of the lifecycle to support post market surveillance activities

- Future enablers: Building on the Joint Plan for Immediate Actions Revision of medical device legislation