Medical Device Vigilance
Current and Future Requirements

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HPRA Medical Devices Information Day

23rd October 2014
Agenda

• Vigilance currently

• Changes in advance of new legislation

• Proposed changes in new legislation
Vigilance Currently
Medical Device Vigilance System

The medical device vigilance system was set up under the medical device directives to minimise risks to the safety of patients, users and others.

‘Well functioning vigilance system is the backbone of a robust regulatory framework in this sector...’

Explanatory Memorandum: European Commission Proposed Regulations 2012/0266
Strengthen, Secure, Rebuild

Confidence
Medical Device Vigilance System

The vigilance system achieves its objectives in the following ways;

• through manufacturers and users submitting vigilance reports to the relevant competent authorities (the HPRA in Ireland);

• through the evaluation of reported incidents or field safety corrective actions by the competent authorities;

• through the dissemination of information, which may be used to prevent recurrence of the incident, or to alleviate the consequences of such incidents, in cases when it’s necessary to do so;

• by the device being updated, modified or taken off the market in cases when it’s necessary to do so.
Year on year increase in the number of medical devices vigilance reports received and assessed.

(Source: IMB Annual Report 2012)
Vigilance Reports

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<thead>
<tr>
<th>Year</th>
<th>Reports</th>
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<tr>
<td>2007</td>
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<td>2008</td>
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<td>2011</td>
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<td>2012</td>
<td>2225</td>
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HSE to review some prostate cancer test results

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3,516 fitted after risks over 'No e PIP risks over 1,700 fitted after risks over

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Joint Plan For Immediate Actions

Improve the functioning of the vigilance system

- Enhanced coordination in analysing reported incidents in order to pool expertise and speed up necessary corrective actions
  - Vigilance teleconferences
  - National Competent Authority Report exchange
Improved Coordination

• Closer coordination between national competent authorities through information exchange and coordinated assessments under the direction of a coordinating authority is fundamental for ensuring a consistently high level of health and safety within the internal market, in particular in the areas of clinical investigations and vigilance.

European Commission Proposed Regulations 2012/0266
Joint Plan For Immediate Actions

• Systematic access for notified bodies to reports of adverse events
  – Proactively highlight issues to Notified Bodies
  – Proactively highlight issues to Competent Authorities

• Encouraging healthcare professionals and empowering patients to report adverse events

• European Commission Joint Research Centre
Focus On Vigilance

• Risk based approach to vigilance assessment
• Detection of signals / adverse trends
• Focus on dissemination of key safety information
• Common problems in reports
Changes in advance of new legislation
2014 - 2015 Changes Vigilance

• Enhanced guidance in area of reporting similar incidents. Clarification on trend reporting

• Move towards event coding and patient outcome coding for vigilance reports

• Enhanced coordination for vigilance activities among competent authorities

• Development of device specific guidance for vigilance reporting

• Move towards more transparency
Changes proposed in new legislation
Proposed Regulation
Chapter VII Vigilance / Market Surveillance

• More specific obligations relating to vigilance system
• Submission through Eudamed
• Dissemination of information through Field Safety Notices
• Coordination role for authorities
• Trend report monitoring and periodic summary report management
• Documentation of vigilance data
• Implementing Acts

• Market surveillance obligations
• Legal tool box
Key Elements in other chapters

- Centralised European Databank (vigilance elements)
  - Serious incidents
  - FSCAs
  - Periodic Summary Reports / Trend Reports
  - Information exchange between CAs
  - Healthcare professionals and public will have appropriate access to the system
- Supply chain traceability to healthcare institution level
- Unique Device Identification
- Summary of safety and clinical performance
Thank you
Questions?