Post Market surveillance and Vigilance

A discussion, some major entities and the IMDRF

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Introduction

- Medical device manufacturer's regulatory obligations continue throughout the device's lifecycle and long after the sale to a customer
- Currently, activities, requirements, definitions and understanding are not harmonised
- Vigilance vs Manufacturers postmarket surveillance duties
  - Processes are interrelated but should be distinguished
  - Postmarket surveillance is a process for understanding experience (NB risk management element) with the device through systematic feedback and review > ISO13485 Sec 8.2.1
  - Post market surveillance – reduce the likelihood of the same adverse incident being repeated in different places at different times
  - Vigilance is the reactive element – acting on reports, communicating with CA on these reports, initiating FCA etc.
- Post market surveillance in Acts, laws ,directives and regs and also ISO13485 and ISO14971,
  - ISO13485 Sec 8.2.1 states the manufacturer "shall establish a documented procedure for a feedback system to provide early warning of quality problems and for input to the corrective and preventive action process"
  - "if national or regional regulations require the organization to gain experience from the postproduction phase, the review of this experience shall form part of the feedback system"

USA FDA – Post market vigilance

- Quality System Regulation Compliance
  - 21 CFR 820 describes the US Federal regulations for medical device quality systems
- The Medical Device Reporting (MDR) regulation (21 CFR 803) provides FDA's device reporting requirements.
- The regulation provides a mechanism to identify and monitor adverse events and certain types of medical device malfunctions with the goal of identifying and correcting medical device problems in a timely manner.
- Reporting requirements for device user facilities, importers manufacturers and distributors, as defined.

USA FDA – Post market vigilance

- Reporting timelines 10/30 days
  - Device contributed to or caused / may have contributed to or caused
- FDA – post approval studies – monitor approved device continued safety and effectiveness and in some cases probable benefit (Class II & III)
  - Failure of device to have serious adverse health consequences
  - Significant use in pediatric populations
  - Implanted for more than a year
  - Life sustaining or supporting and used outside of a facility
- Specific mention of cybersecurity – FDA guidance on management of cybersecurity in medical devices

USA FDA – UDI

- Matches world wide regulatory effort for an identification system to improve several key Postmarket activities
  - Medical errors from device misidentification
  - More accurate adverse event reporting, making device easier to identify
  - Use AE information more rapidly to take appropriate, focused action
  - Secure global supply chain and counterfeiting prevention

USA FDA – Medical device recalls

- *"Recall"* – means a firms removal or correction of a marketed product that FDA considers to be in violation of the laws it administers against which the agency would initiate legal action.
  - "*Correction"* – means repair, modification, adjustment, relabeling, destruction or inspection (including patient monitoring) of a product without physical removal to some other location
  - "*Removal"* – means physical removal of a device from its point of use to some other location for repair….
- "*Market withdrawal*" – is a correction or removal of a distributed device that involves a minor violation that would not be subject to legal action by the FDA
- Three classes
  - Class I – use or exposure to the device will cause serious adverse health consequences or death
  - Class II - use or exposure to the device may cause temporary or medically reversible adverse health consequences or probability is remote
  - Class III - use or exposure to the device is not likely to cause adverse health consequences

Health Canada

- Protecting Canadians from unsafe drugs act (Vanessa's law) Bill C-17 includes medical devices
- Requirement for implant registration – MDR schedule 2 listing
  - Implant card – certain requirements
- Complaint handling procedure
  - Issues of quality and compliance
  - Assessing device conformance to claims relating to effectiveness and performance characteristics
  - Develop the appropriate corrective and preventive action
    - Increased device post market surveillance
    - Product design or manufacturing change
    - Recall
  - Determining reportability to Health Canada

Health Canada

- Mandatory reporting > all three requirements to be met
  - Occurred inside or outside Canada
    - If outside Canada – only if the manufacturer has informed the in country reg auth that corrective action will be taken
  - Related to a device failure or deterioration in its effectiveness, or inadequacy in it’s labelling or directions for use
  - Led to the death or serious deterioration of a patient user or other person, or could do so if it were to recur
  - “Sold” also means “authorised for sale”
  - Preliminary and final reports (preliminary proposes the timeline for the final report
  - 10 and 30 day timelines: death or serious injury > possibility of death or serious injury

EU – Post Market surveillance

- Manufacturers are required to put in place a systematic procedure to review device experience on the postproduction phase
  - Proactive (seeking) and reactive (collecting and assessing complaints)
    - Customer user surveys
    - Adverse incidents
    - Product reports and feedback
    - Customer complaints
    - Customer requirements
    - Patient follow up clinical trials
    - Services and evaluation reports
    - Scientific papers

EU – Post Market surveillance

- Types of incidents
  - Incidents resulting in death of patient, user or other person
  - Incidents resulting in serious deterioration in a patient, user or other person's state of health.
  - Events that might have led to death or serious deterioration in the state of health
- Criteria for reporting
  - Event occurred
  - Manufacturers device is considered a contributory cause
  - Event led or might have led to type of incident above
- Exclusions – 8 exclusions
- Reporting timelines
  - 2 days for serious public health threat
  - 10/30 days > caused / might have caused (EUMDR 30days shortened to 15)
- EU MDR – "statistically significant increase" reporting – frequency or severity – manufacturers need to define – irrespective of PSR

EU – EUDAMED

- Central European Databank for medical devices allowing CA transparency and coordinate device directives enforcement e.g. post market requirements
- Under EUMDR Eudamed expanded role – enhances CA coordination
  - More information on device traceability, certificates and clinical studies
  - Eudamed will also play a role in informing the public (safety and clinical performance
  - EUMDR May 2021 > Eudamed3 May 2022
    - UDI; certification (CE); Manufacturers SRN market surveillance data etc.
  - Member state may implement special controls

IMDRF

- Postmarket definition varies from regulator to regulator, generally proactive activities carried out by (manufacturer or regulator) to gain information about the quality safety or performance of marketed medical devices
  - CA > testing; product review; other controlling measures
- Modifications in EU MDR to be in line with IMDRF (GHTF) policies are a sign of willingness to converge
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- Predisposition to report than not report

Conclusion

- Post market surveillance system is important for better health and safety protection of patients, users and others, reducing the likelihood of the incidents recurrence
- Manufacturers are required to implement a PMS system to monitor post production performance in a proactive and systematic manner according to the applicable medical device laws and regs.
- Achieved by evaluating incidents and disseminating information as appropriate to prevent repetition of similar incidents or alleviate an incidents consequences.
- Update Technical files; reporting vigilance events; conducting FCA; maintaining PMS; abiding by laws and regulations
- Update QMS; perform internal audits and ensure device safety and performance levels are maintained
- *Postmarket lifecycle management may be the most resource-intensive phase for MD manufacturers*