
QUALITY


RISK MANAGEMENT


COMPETITIVE ADVANTAGE


EXPERTISE


MARKET INTELLIGENCE


FURTHER EXCELLENCE


REGULATORY COMPLIANCE


SPEED TO MARKET


PATIENT SAFETY

If a recall has to be announced…

Medical and legal aspects of serious implant failures

Orthopaedica Belgica 2019 Congress
25 April 2019

WHEN YOU NEED TO BE SURE

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Involvement of the Notified Body: Current regulatory requirements

- Current legislation Medical Device Directive MDD 93/42/EEC
  - Article 10: "Information on incidents occuring following placing of devices on the market"

  ⇒ no word about involvement of the Notified Body who certified the medical device

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Involvement of the Notified Body: Current regulatory requirements

MEDDEV 2.12.1- rev 8 (2013):

Guidelines on a Medical Devices Vigilance System

- Notified Bodies do not play a key operational role in the Vigilance System
- Manufacturers:
  - must keep the Notified Body advised of issues occurring in the post production phase affecting the certification.
  - must keep the Notified Body advised of relevant changes
- Notified Body involved in the certification:
  - recommended to inform them about the Field Safety Corrective Action.
  - recommended to sent them a copy of the Field Safety Notice.
  - National Competent Authority: liaison/consulting may be needed with them on initiative of the NCA

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Involvement of the Notified Body: Current regulatory requirements

MEDDEV 2.12.1- rev 8 (2013):

Guidelines on a Medical Devices Vigilance System

- however, the Notified Body is involved:
  - Assessment of vigilance procedures
  - audit of the implementation of the vigilance procedures, and link with other systems e.g. Corrective and Preventive Action (CAPA) , FSCA
  - Assessment of the impact of vigilance issues on the certification granted
  - Liaise with the National Competent Authority if required

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Involvement of the Notified Body: Current regulatory requirements

NBOG's Best Practice Guide:

Role of Notified Bodies in the Medical Device Vigilance System (2009)

- No particular role in the investigation or the evaluation of the incident
- but Notified Body should know about such events and any corrective or preventive action taken by the manufacturer
  - to prevent a recurrence of the incident
  - to assess the impact of vigilance issues on the certifications granted.
- The Notified Body shall not interfere with the Competent Authority, when the CA is
  - monitoring,
  - commenting or
  - challenging the manufacturer's incident investigation and conclusions.

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Involvement of the Notified Body: near future regulatory requirements

Medical Device Regulations MDR 2017/745

Chapter VII: Post-Market surveillance, vigilance and market surveillance.

- **post-market surveillance**: preventive or corrective action: manufacturer shall implement the appropriate measures and inform the competent authorities concerned and, where applicable, the notified body.
- **Reporting of serious incidents and field safety corrective actions :** no obligation on reporting to the Notified Body
- **Periodic safety update report** (class III devices or implantable devices) The notified body shall review PSUR and add its evaluation to that electronic system with details of any action taken.

Involvement of the Notified Body: near future regulatory requirements

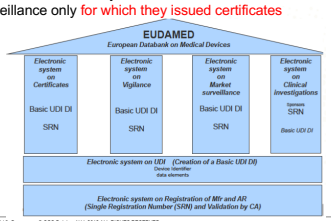
Medical Device Regulations MDR 2017/745

Chapter VII: Post-Market surveillance, vigilance and market surveillance.

- **trend reports** The competent authorities may conduct their own assessments on the trend. Competent authority shall inform Commission, other competent authorities and the notified body that issued the certificate, of the results of such assessment and of the adoption of such measures.
- **Analysis of serious incidents and field safety corrective actions** The manufacturer shall co-operate with the competent authorities and where relevant with the notified body concerned during the investigations.

Involvement of the Notified Body: Eudamed database

- Eudamed database: some parts accessible by Notified Bodies
  - Vigilance system:
    - view post-market surveillance and vigilance information for devices for which they issued certificates
    - Periodic Safety Update Report: add evaluation to PSURs submitted by manufacturers
  - Market Surveillance System: view and transmit information on market surveillance only for which they issued certificates



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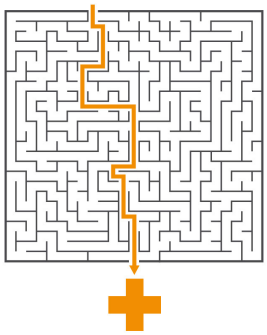

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