EUMDR – the final countdown

practical impact on manufacturers

Roger Kessels
Disclosure

I have the following potential conflicts of interest to report:

☐ Consulting
☐ Employment in industry
☐ Stockholder of a healthcare company
☐ Owner of a healthcare company
☐ Other(s)

☐ I do not have any potential conflict of interest
EU Medical Device Regulation
2017/745

• Will replace the Medical Device Directive (93/42/EEC or MDD).

• Compliance to the new regulation is required to (continue to) sell medical devices in the markets where CE marking is necessary.

• EU MDR is intended to ensure high standards of quality and safety for medical devices being produced in or supplied to Europe, and increase transparency to users and patients.

• Important concepts in MDR
  – Clinical evaluation
  – Traceability
  – Postmarket surveillance
  – Person Responsible for Regulatory Compliance
  – EUDAMED
The combined impacts from EU MDR are significant to a medical devices company from a commercial, portfolio, R&D, process, and organizational perspective.
Impact on the manufacturers

- Product portfolio need thorough review and assessed against EU MDR
- Reassess of labeling and packaging artwork processes to ensure compliance
- Maintain their current certificates until they expire, but if manufacturer make ‘significant change’ after May 2020, need to comply to new requirement.
- Requirement on equivalence is high. Device should have the same technical, biological, and clinical characteristics, and demonstrate sufficient access to the technical file of the equivalence device.
- Mandate to use web-based portal for economic operators and notified bodies to provide data to users and/or patients
Impact on the manufactures

• No grandfathering of legacy devices into compliancy.

• Clinical evaluations content and acceptability is changing.

• Clinical investigation is obligatory for class III and implantable devices.
  – Exceptions under strict conditions

• Post-market requirements beyond complaint handling
  – safety update reports, PSUR.
  – post-market surveillance plans
  – Post-market clinical follow-up, PMCF
Manufacturer’s challenges

• Changes indirectly or directly affect the entire quality management system

• Many manufacturers are not using dynamic templates to support label printing. Updates, validation, workflow and approval process may prove to be challenging and time consuming process.

• Lack of sufficient resources to process requirements for compliance in the time.

• Pressing demand to focus on EU MDR results in reprioritizing and/or delaying other project initiatives

• Uncertainties on data submissions to EUDAMED introduces risk, delay, and potential non-compliance to documentations under preparation.
Manufacturer’s preparedness

- Internal resources are at a peak and time for compliance is getting scarce.
  - help from external resources for expertise and solutions needed to comply with these evolving regional and international regulations.

- Manufacturers are revamping existing processes and system
  - To be prepared for the future

- Clinical evidence scrutiny demands identifying sources of clinical data beyond clinical study design
  - Ongoing clinical programs that could provide the evidence in due time
  - National registries, such as the NCDR Registry, the Cath PCI registry, the PVI registry, and VQI registry
  - Collect/Appraise data from these sources and update CER for submission to get MDR certificate.
Moving parts

• European Database on Medical Devices (EUDAMED)
  – The implementation of the European Database for Medical Devices (EUDAMED) is delayed by two years

• Limited number of Notified Bodies Designated Under the EU MDR (2017/745) (status 7 January, 2020)
  – BSI Netherlands – 2797
  – BSI UK – 0086
  – DARE!!! Services – 1912
  – DEKRA Certification BV – 0344
  – DEKRA Certification GmbH – 1024
  – IMQ S.p.A – 0051
  – MEDCERT ZERTIFIZIERUNGS- UND PRÜFUNGSGESELLSCHAFT FÜR DIE MEDIZIN GMBH – 0482
  – TÜV Rheinland LGA – 0197
  – TÜV SÜD – 0123 (MDR scope)
Thank you
EUMDR – the final countdown

practical impact on manufacturers

Roger Kessels