Post-market Surveillance

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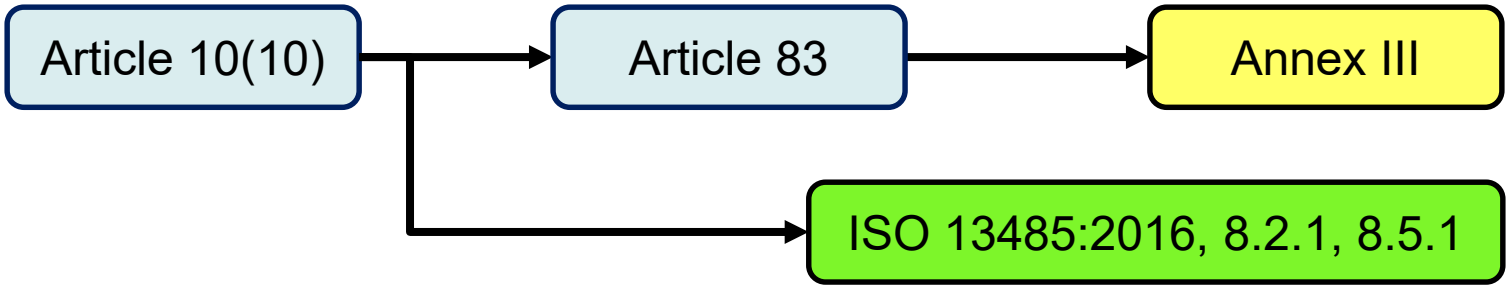
FDANEWS

Topics

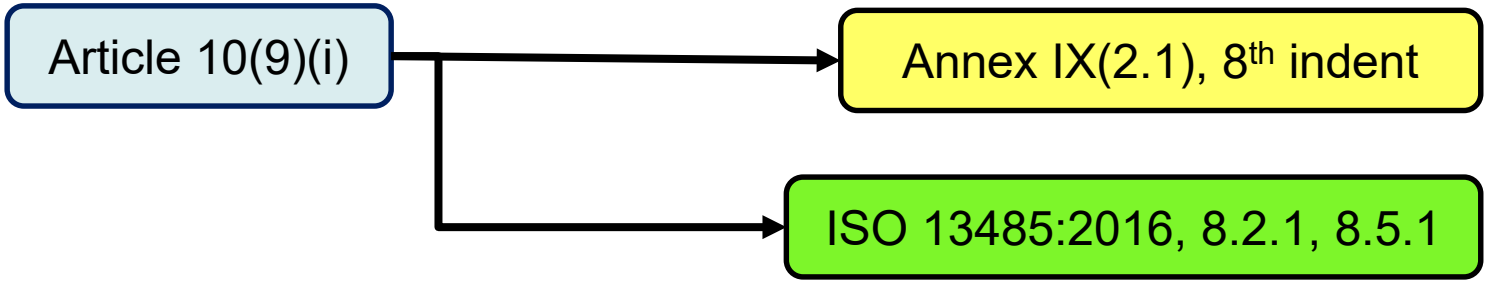
- PMS Overview
- PMS Plan
- PMS Report
- Periodic Safety Update Report (PSUR)
- Linkage to Other Activities
- Exercise C1 – Developing Elements of the PMS Plan
- Exercise C2 – Creating and Updating the PSUR
- Questions

PMS Overview

PMS



Clinical Evaluation as Part of the QMS



Definitions

- *Post-market Surveillance* means all activities carried out by manufacturers in cooperation with other economic operators to institute and keep up to date a systematic procedure to proactively collect and review experience gained from devices they place on the market, make available on the market or put into service for the purpose of identifying any need to immediately apply any necessary corrective or preventive actions [Art. 2(60)]

- *Market Surveillance* means the activities carried out and measures taken by competent authorities to check and ensure that devices comply with the requirements set out in the relevant Union harmonization legislation and do not endanger health, safety or any other aspect of public interest protection [Art. 2(61)]

Article 83 & 84

- For each device, plan, establish, document, implement, maintain, and update a post-market surveillance system in a manner that is proportionate to the risk class and appropriate for the type of device.
- The PMS system is an integral part of the manufacturer's quality management system referred to in Article 10(9).
- The post-market surveillance system referred to in Article 83 is based on a post-market surveillance plan (see Annex III(1.1)).
- The post-market surveillance plan is part of the technical documentation specified in Annex II.

Article 85

- Manufacturers of Class I devices prepare a post-market surveillance report summarizing the results and conclusions of the analyses of the post-market surveillance data gathered as a result of the post-market surveillance plan referred to in Article 84 together with a rationale and description of any preventive and corrective actions taken.

- The report is updated when necessary and made available to the competent authority upon request

Article 86

- Manufacturers of Class IIa, Class IIb and Class III devices prepare a periodic safety update report ('PSUR') for each device and where relevant for each category or group of devices.

- Manufacturers of Class IIa devices update the PSUR at least every two years.
- Manufacturers of Class IIb and Class III devices update the PSUR at least annually.

- For Class III devices or implantable devices, manufacturers submit PSURs electronically to the Notified Body. The Notified Body reviews the PSUR and sends it to the Competent Authority.

- For other devices, manufacturers make PSURs available to the Notified Body and, upon request, to Competent Authorities.

Summary of Safety and Clinical Performance (SSCP)

Article 32(1)

- For implantable devices and for Class III devices, the manufacturer prepares a Summary Of Safety And Clinical Performance
  - It is written to be clear to the intended user and, if relevant, to the patient and is made available to the public via Eudamed

- The draft of the Summary Of Safety And Clinical Performance is part of the shall be part of the documentation submitted to the Notified Body as part of conformity assessment.

- The Notified Body validates the summary and uploads it to Eudamed.

- The manufacturer mentions on the label or instructions for use where the summary is available.

Article 32(2)

- The SSCP includes:
  - Identification of the device (including the basic UDI-DI) and the manufacturer (including the SRN)
  - The intended purpose of the device and any indications, contraindications, and target populations
  - A description of the device including previous generations, variants, accessories, or other devices used in combination
  - Possible diagnostic or therapeutic alternatives
  - Reference to any harmonized standards and CS applied
  - A summary of the clinical evaluation and relevant information on PMCF
  - Suggested profile and training for users
  - Information on any residual risks and any undesirable effects, warnings, and precautions

PMS Plan

PMS Plan

- Article 84 Post-market Surveillance Plan
  - The PMS system in Article 83 is based on the PMS Plan
  - Annex III(1.1) has the requirements for the plan
  - Annex II, the technical documentation, includes the plan

PMS Plan

- Annex III Technical Documentation on Post-market Surveillance
  - Section 1.1 has two major sections
  - Section 1.1(a) describes the collection and utilization of specific information
  - Section 1.1(b) describes the required elements in the plan

Definitions

- *Incident* means any malfunction or deterioration in the characteristics or performance of a device made available on the market, including use-error due to ergonomic features, as well as any inadequacy in the information supplied by the manufacturer and any undesirable side-effect [Art. 2(64)]

- *Serious Incident* means any incident that directly or indirectly led, might have led, or might lead to any of the following:
  (a) the death of a patient, user, or other person
  (b) the temporary or permanent serious deterioration of a patient's, user's, or other person's state of health
  (c) a serious public health threat [Art. 2(65)]

- *Serious Public Health Threat* means an event which could result in imminent risk of death, serious deterioration in a person's state of health, or serious illness, that may require prompt remedial action, and that may cause significant morbidity or mortality in humans, or that is unusual or unexpected for the given place and time [Art. 2(66)]

Annex III(1.1)(a)

- The PMS Plan information collection (partial list):
  - Information on serious incidents
    - Periodic Safety Update Report, PSUR, or Field Safety Corrective Action, FSCA
    - A proactive and systematic process to collect information
  - Information on non-serious incidents
  - Information on undesirable side-effects
  - Information on trend reporting

Annex III(1.1)(b)

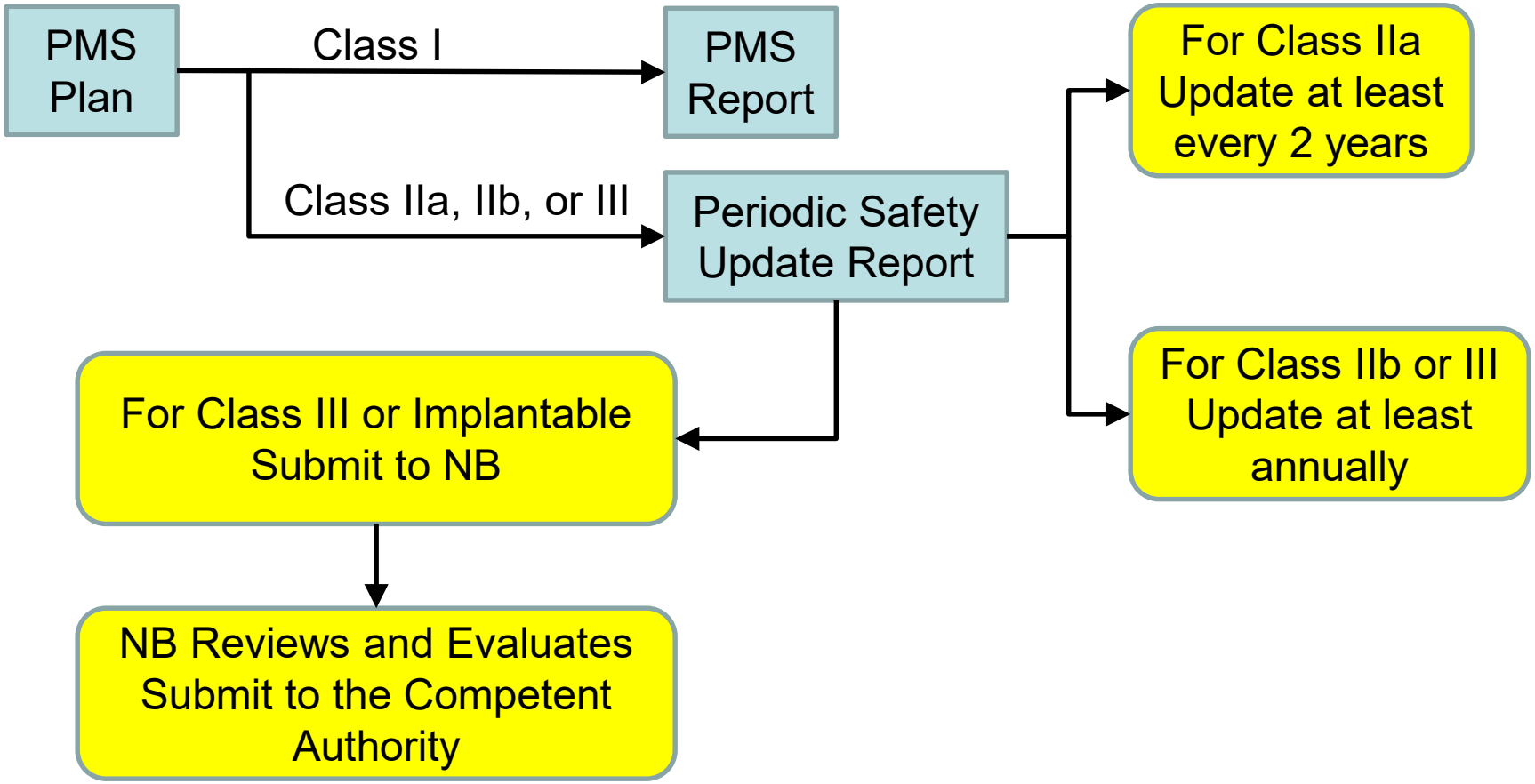
- The PMS Plan covers (partial list):
  - A proactive and systematic process to collect information
  - Effective and appropriate methods and processes to assess the collected data
  - Suitable indicators and threshold values for reassessment of the benefit-risk analysis and risk management
  - Effective and appropriate methods and tools to investigate complaints and analyze market-related experience collected in the field
  - Methods and protocols to manage the events subject to trend report, including methods and protocols to establish any statistically significant increase in the frequency or severity of incidents as well as the observation period
  - The PMCF plan (see Annex XIV, Part B) or a justification as to why a PMCF is not applicable

Plans Inside Plans

- The PMS plan contains two other plans
- Methods and protocols for trend reporting
  - Methods and protocols for to detect a statistically significant increase in the frequency or severity of incidents including the observation period
- The Post-market Clinical Follow-up plan from Annex XIV

Reports

Report Diagram



PMS Report

- Article 85 Post-market Surveillance Report
  - Applies to Class I devices only
  - Analyze the data collected from the PMS Plan
  - Summarize the results and conclusions
  - Describe any corrective or preventive action taken with a rationale
  - Update when necessary
  - Make available to the Competent Authority upon request

PSUR

- Article 86 Periodic Safety Update Report
  - Applies to Class IIa, IIb, and III devices only
  - Describe any corrective or preventive action taken with a rationale
  - Provide the conclusions of benefit-risk determination
  - Provide the main findings of the PMCF
  - Provide the sales volume, the user population characteristics, and the usage frequency
  - For Class IIa devices update at least every two years
  - For Class IIb or III devices update at least annually
  - For Class III or implantable devices, submit electronically to the NB
    - NB reviews, evaluates, and makes them available to the Competent Authority

Electronic System

- Article 92
- The electronic system, Eudamed, process the PSURs

- The information is available the Competent Authorities and to the Commission

- The Commission may make some Eudamed information available to health care professions or to the general public

- The Commission may, based on reciprocity, make the Eudamed information available to third country regulators or to international organizations

Linkage to Other Activities

Linkage to ISO 13485:2016

- Article 10(10) requires the manufacturer to implement a PMS system following Article 83

- CEN/TR 17223:2018 links the PMS to ISO 13485:2017, 8.2.1 & 8.5.1
  - 8.2.1 Monitoring and Measurement – Feedback
  - 8.5.1 Improvement – General
  - Partially covered. ISO 13485:2016 requires a system of post market surveillance in accordance with regulatory requirements within the quality management system. The detail in Article 83 is not covered explicitly.

ISO/AWI TR 20416

- ISO/AWI TR 20416 Medical devices – Post-market surveillance for manufacturers

- prCEN ISO/TR 20416 Medical devices – Post-market surveillance for manufacturers
- The proposed Technical Report is to provide a common understanding of post-market surveillance, or PMS facilitating international cooperation in this area. The Technical Report is intended for use by manufacturers of medical devices. With PMS, the manufacturers can collect, evaluate, and analyze experience gained with their devices after placing on the market. The resulting information can be used for, among others, improvement of the devices. The proposed Technical Report aims to describe a comprehensive data collection process and activities that allow characterization of the behavior of the devices as used in practice, and identify necessary and/or possible actions. PMS information may include material that requires reporting to Regulatory Authorities. The proposed Technical Report will not provide information for such reporting, nor for achieving compliance with any other (PMS) requirement by Regulatory Authorities. Market surveillance by national authorities, as well as actions legally required to be performed by manufacturers as part of PMS or vigilance are outside the scope of the proposed Technical Report. The document is not intended to replace or change national or regional legislation on PMS.

PMS Data Usage

- Article 83(3) lists places to use the PMS data
  - Update the benefit-risk determination
  - Improve risk management
  - Update design, manufacturing, labeling, and the IFU
  - Update the clinical evaluation
  - Update the Summary of Safety and Clinical Performance, SSCP
  - Identify the need for corrective action, preventive action, and filed safety corrective action
  - Improve usability, performance, and safety of the device
  - Contribute to the post-market surveillance of other devices

Exercises

Exercise C1

- Developing Elements of the PMS Plan
- Use a hypothetical device to develop effective and appropriate methods and tools to investigate complaints.

Exercise C2

- Creating and Updating the PSUR
- Use a hypothetical device to determine the volume of sales of the device, estimate the size and other characteristics of the population using the device and, where practicable, the usage frequency of the device.

QUESTIONS