Annex III

Post Market Surveillance (PMS) and Technical Documentation (TD)

Previously in the Directive 93/42/EEC ‘Post Market Surveillance’ appeared once, twice, maybe three times …The Regulation mentions it more than 60 times!

The increased focus is clear to all and especially manufacturers of devices class IIa and higher should be aware of the new requirements.

As we all know PMS can be used for good business or can be really bad business, depending on how you handle it.

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Annex III: Market Surveillance (PMS) and Technical Documentation (TD)

The matter of PMS is not new, hence, some of the aspects from Annex III and the related articles are the same or similar to what NBs have been requiring previously, however, the MDR is very explicit on requirements.

PMS is required to be an integral part of the manufacturers Quality Management System (QMS) for each device and should be appropriate for the type of device and thereby reflect the risk class.

The PMS system (art. 83) shall gather, record and analyze data on the quality, performance and safety of a device throughout its lifetime.

A PMS Plan is still required

As previous, a PMS Plan is required (not for custom made devices).

This should include a Post Market Clinical Follow Up (PMCF) Plan.

For Class IIa/IIb/III devices Product Safety Update Reports (PSURs (art. 86)) are required. For Class I only PMS Reports (art. 85) are required

PSUR is new for medical devices, known from medicinal products.

Data shall be used to **update**:

a) The benefit-risk determination and improve the Risk Management (RM);

b) The design, manufacturing info, IFU, and labelling;

c) The clinical evaluation;

d) The summary of safety and clinical performance (Only implantable and class III, (art. 32)).

Further data shall be used to **identify**:

e) Needs for preventive, corrective or field safety corrective action;

f) Options to improve the usability, performance and safety of the device;

h) Trends (in accordance with (art. 88)).

g) And when relevant; to contribute to the PMS of other devices. The TD shall be updated accordingly.

The regulation specifically lines up which elements are required in the TD.

The PMS Plan must specify:

The PMS Plan must specify how, from where, and how frequently data is collected, and be a proactive and systematic process including effective and appropriate methods and processes to assess the collected data.

Further it shall address the following;

- Information concerning serious incidents, including information from PSURs, and field safety corrective actions;
- Records referring to non-serious incidents and data on any undesirable side-effects;
- Information from trend reporting;
- Relevant specialist or technical literature, databases and/or registers;
- Information, including feedbacks and complaints, provided by users, distributors and importers; and
- Publicly available information about similar medical devices.

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The PMS Plan shall cover at least

- Correct characterization of the performance of the devices and shall also allow a comparison to be made between the device and similar products available on the market;
- Suitable indicators and threshold values that shall be used in the continuous reassessment of the benefit-risk analysis and of the RM as referred to in Section 3 of Annex I (Appendix A);
- Effective and appropriate methods and tools
  - to investigate complaints and analyze market-related experience collected in the field;
  - to trace and identify devices for which corrective actions might be necessary; and
- Methods and protocols
  - to manage the events subject to the trend report as provided for in art.88,
  - to be used to establish any statistically significant increase in the frequency or severity of incidents as well as the observation period;
  - to communicate effectively with competent authorities (CA), notified bodies (NB), economic operators and users;

- Reference to procedures to fulfil the manufacturers obligations in relation to the PMS system (art. 83) and Plan (art. 84) as well as the PSUR (art. 86).
- Systematic procedures to identify and initiate appropriate measures including corrective actions;
- A PMCF plan as referred to in Part B of Annex XIV, or a justification as to why a PMCF is not applicable.
- The PSUR (art. 86) and the PMS Report (art. 85).

Be aware to not confuse the definitions

‘Post Market Surveillance’
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.

‘Market Surveillance’
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.

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Relevant Articles in Short

The articles not covered in the text is covered below:

Art. 32 Summary of safety and clinical performance:
Shall be clear and understandable to the intended user and/or patient and available via Eudamed. IFU or label of device must specify where this is available. The NB validates the summary and uploads it to Eudamed.

Summary shall include at least; device and manufacturer identification (Basic UDI and SRN); intended purpose; (contra)indications; population; description of: device, difference to older version, accessories and other devices to be used with device. Alternatives, harmonized and common standards applied, Clinical evaluation summary and PMCF information, user profile (incl. training), residual risks, undesirable effects, warnings and cautions.

Art. 83 PMS System:
Manufacturers must, for each device, plan, establish, document, implement, maintain and update a PMS system. The system shall be suited to draw the necessary conclusions and to determine, implement and monitor any preventive and corrective actions.

If there is a need for preventive or corrective action, appropriate measures shall be implemented and the CAs concerned and, where applicable, the NB shall be informed.

Where a serious incident is identified or a field safety corrective action is implemented, it shall be reported in accordance with art. 87.

Art. 84 PMS Plan:
The PMS system shall be based on a PMS Plan.

Art. 85 PMS Report:
Summary of results and conclusions of the analyzed PMS data incl. rationale and description of any preventive and corrective actions taken. The report must be made available to the CA upon request.

Art. 86 PSUR:
A summary as for the PMS Report. Further, it shall set out the benefit-risk determination, the main findings of the PMCF, sales volume and an estimate of the size and other characteristics of the population and, where practicable, the usage frequency of the device.

PSUR shall be updated annually (class IIb and III) and biannually for class IIa.

For class III or implantable devices, PSURs shall be submitted electronically (EUDAMED art. 92) to the NB who shall review the PSUR and add its evaluation. The PSUR and NB evaluation shall be made available to CA through EUDAMED. PSURs for all other devices than class III shall be available to NB and CA, upon request.

Art. 88 Trend Reporting:
Report electronically (EUDAMED art. 92) any statistically significant increase in the frequency or severity (in respect of the device/ category/ group of devices during a specific period as specified in the TD and product information) of not serious incidents or undesirable side-effects that could have a significant impact on the benefit-risk analysis and which have led or may lead to unacceptable risks to the health/safety of patients, users or other persons.

The PMS Plan must specify how to manage these, the methodology used for determining these, and the observation period. The CAs may conduct their own assessments on the Reports and require the manufacturer to adopt appropriate measures.

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Take Aways

- Devices CE marked under the Directive 93/42/EEC must STILL comply to Regulation requirements with regards to PMS requirements by 2020.

- The MDR has two new aspects which have to be part of the Technical Documentation (TD) that were not covered (directly or indirectly) by the MDD.

  These are the Product Safety Update Reports (Class IIa, IIb, and III) and the Summary of Safety and Clinical Performance (class III and implantable devices).

- The Technical Documentation (TD) shall be presented in a clear, organized, readily searchable and unambiguous manner and shall include in particular the elements described in this report and be in accordance with art. 83-86.

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Our employees have more than +25 years of experience with the full lifecycle of RA/QA within the medical device area. We pride ourselves of being on the forefront of legislation and interpretation of what is the impact for manufacturers and economic operators.

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