PMS report

LVL Ophtalmo - PMS report

Device type: lenses AB

Complaints : no complaints received in 2017 - 2018

Vigilance: no incidents has been occurred in past 2 years

Customer feedback: customer satisfaction analysis was conducted last year and showed that customers were satisfied.

NC products : 1 NC was received on damaged transport carton, no risk on final product.

Conclusion : Based on the evidence gathered during last 2 years, there is no new or unidentified risk and we may conclude that the risk - benefit ratio is excellent.

signed

CEO LVL Ophtalmo

PMS - PMCF preparation

EFCLIN Congres - 27/4/2019

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PMS

Post-market Surveillance allows for a longitudinal view over time of the safety performance of a medical device or IVD and should allow the manufacturer to ensure that their MD’s/IVD’s are at least as safe for patients as they were when first placed on the market.

A manufacturer shall know at all times how his product performs in the field !

MDD 93/42/EEC versus MDR

	MDD 93/42/EEC	MDR	Rate
Pages	60	175	2,9
PMS term being used	2	66	33

Relevant additional terms throughout the MDR

- Post-market clinical follow up (PMCF)
- Post-market surveillance system (PMS)
- Post-market safety-related activities
- Post-market phase
- Post-market experience
- Post-market surveillance plan
- Post-market surveillance obligations
- Post-market surveillance activities
- Post-market surveillance report
- Periodic Safety Update report (PSUR)
- Post-market surveillance data
- Post-market information

Market Surveillance = means the activities carried out and measures taken by competent authorities

PMS - Definition

art1 - (60)

PMS 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

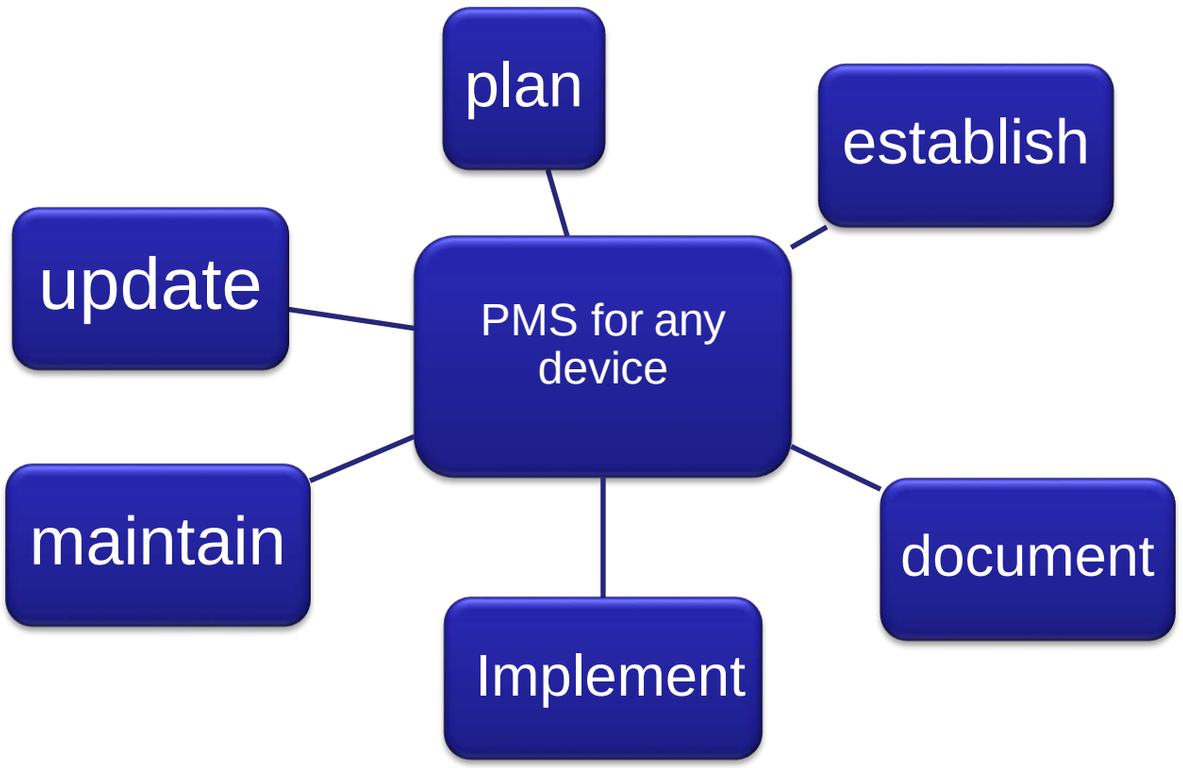
- devices they placed on the market,
- make available on the market or
- put into service

art. 15 : The person responsible for regulatory compliance shall at least be responsible for ensuring that: (c) the post-market surveillance obligations are complied with in accordance with art 10 (general obligation of the manufacturer)

PMS regulatory req.

- MDR chapter VII (art 83 - 86) on PMS
- annex III (PMS technical documentation)
- Annex XIV (clinical evaluation and PMCF)

- For each device or subcategory, manufacturers shall 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.



- That system shall be an integral part of the manufacturer's quality management system

The degree of PMS depends on:

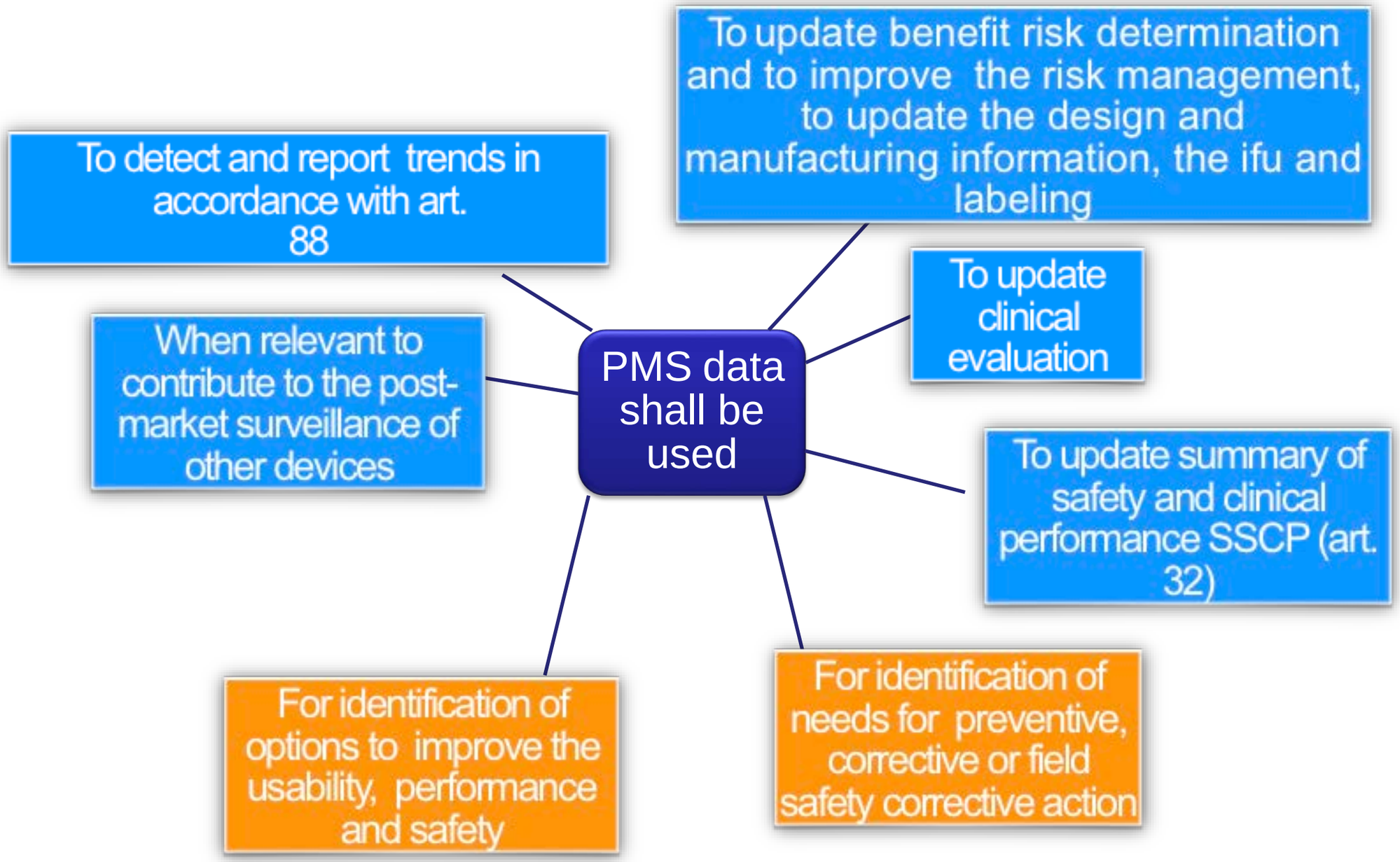
A. Device classification (risk)
B. Novelty of the device
C. Lifetime of the device

A. Clinical risks (as in IFU warning, precautions, contraindications, adverse reactions, ….)
User risks - usability risks

C. New features, new indications, new performance claims , …

E. Data on the quality, performance and safety of a device throughout its entire lifetime (Implants , reusable , ….)

Purpose of the PMS (Art. 83-3)

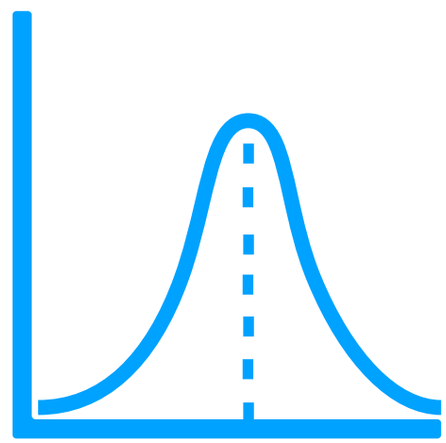


Purpose has to be included in your PMS report - PSUR report !

PMS plan

- Planning involves
  - WHO (Responsibility)
  - WHAT - HOW (reference to procedures , work instructions, how data is to be captured, archived, analysed, …
  - WHEN (planning, frequencies,…

PMS plan shall be part of the Technical documentation !
Systematic approach !



involvement of statistical techniques

PMS PLAN

Reactive - Passive

Quality

complaints

vigilance
incident /
FSCA / FSN

Customer
service

Proactive PMS

PMCF

**Proactive
clinical
Data
acquisition**

literature

Customer /
user
surveys….

PMS PLAN

NBMED 2.12

Reactive - Passive

Quality

complaints

vigilance
incident /
FSCA / FSN

Customer
service

ISO 13485

Meddev 2.12/1

Proactive PMS

Meddev 2.12/2

PMCF

**Proactive
clinical
Data
acquisition**

literature

**Meddev
2.7.1**

Proactive PMS Input

Reactive

- Customer complaints
- Unsolicited user feedback (other than complaints)
- Maintenance/service reports
- In-house testing (routine)
- Failure analysis

Proactive

- Customer surveys
- Post CE mark clinical trials, including PMCF
- Manufacturer sponsored device tracking/implant registries
- Expert user groups (focus groups)
- Social media
- Literature reviews
- Regional or national device registries
- (non-manufacturer sponsored trials)
- …

Reactive PMS

- Complaint analysis : analysis following your identified risk.
  - New risk ?
  - frequency of risk
  - probability of risk confirmed ?
- Complaint = much broader definition —> PMS case : FAQ, user / doctor questions, logistic, service , …

Proactive On Technical items

- Literature reviews
- product guidance documents (CS, product recommendations, international product technical norms, evidenced based clinical guidance documents from health organisations / health authorities, …)
- Client investigations - failure analysis Registries (implants)
- follow up on known (non manufacturer sponsored) clinical trials
- Active device tracking
- Post CE clinical trials (PMCF)
- Experience on equivalent devices reports
- ….

Proactive On Quality control

- Product Testing
- ongoing testing on shelf life
- Performance Trend analysis (consider statistical techniques following ISO 13485)
- Internal Product audits
- Other bodies (the CA)

Proactive On services

- On services (installation and servicing report analysis)
- Returns
- Warranty Claims
- Repairs
- Field Service
- User reactions during training programs, product information to lay users, (if no servicing is conducted)
- …

Proactive On Marketing

- Market studies, equivalence studies,
- Competitors information (publicly available- IFU - Label - claims - …
- Website information feedback, FAQ , Sales Call Feedback, …
- Social media user groups (identified ?, feedback ?, …)

- Customer surveys experiences.
- Usability studies (how used, misuse, off label use, feedback on instructions for use, trining needs for users,

- Specific Post market study to gather clinical data —> PMCF
- Reps or Distributor Feedback —> needs input from distribution channel / economic operators
- The (social) Media
- Expert user groups / organisations / key users
- ….

PMS PLAN

PMS plan also includes (or make reference to it)

- Processes to collect data … also allow a comparison to be made between the device and similar products available on the market (literature search, database search, ….
- Processes to assess the collected data;
- methods and protocols to communicate effectively with CA-NB -economic operators
- methods and protocols to manage the events subject to the trend report (establish statistical significant increase in frequency , severity …
- methods and tools to investigate complaints or market experiences
- to arrange indicators and threshold values that shall be used in reassessment of the benefit-risk analysis (risk evaluation, frequency, severity, …)
- ….

PMS team

Effective PMS System - PMS team

product analysis

Conferences
key users

Quality

Customer

Production &
Process controls

PMS Management

Product design :
IFU - Product
labelling - …
User interface - …
Risk analysis

Literature review

Marketing
Market research
competitors

Clinical studies

service feed back
Complaints

PMS output - PSUR

- PSUR reporting (periodic safety update report)
  (for class I = PMS report)

- PSUR reports to make available for NB , CA

- for class III and class IIB : PSUR annually (for other other classes every 2 years)

- PSUR is part of your Technical documentation

- for class III or implantable : PSUR + SSCP (summary of safety and clinical performance) to be uploaded in Eudamed annually

PSUR pharma ?

- Equivalance to PSUR pharma ?

Guideline on good pharmacovigilance practices (GVP)

Module VII – Periodic safety update report (Rev 1)

https://www.ema.europa.eu/en/human-regulatory/post-authorisation/pharmacovigilance/good-pharmacovigilance-practices#final-gvp-annex-ii---templates-section

- Table of content : 20 points.
  (including volume of sales , use , findings of PMCF,…)

- No Template - guideline yet available

PMS output

<u>Purpose of PMS in art 83- point 3</u>
(a) to update the benefit-risk determination and to improve the risk management as referred to in Chapter I of Annex I;
(b) to update the design and manufacturing information, the instructions for use and the labelling;
(c) to update the clinical evaluation;
(d) to update the summary of safety and clinical performance referred to in Article 32;
(e) for the identification of needs for preventive, corrective or field safety corrective action;
(f) for the identification of options to improve the usability, performance and safety of the device;
(g) when relevant, to contribute to the post-market surveillance of other devices;
(h) to detect and report trends in accordance with Article 88.

—> This should be reflected in your PSUR conclusions

PSUR report

- PSUR will be reviewed by independent persons with or without knowledge of your device.

- NEEDS Documented evidence !

- Be clear and understandable.

- Make it as a “stand alone document”.

- Be very clear of not conducting PMCF

PMCF

- **PMCF – intended to answer specific questions relating to clinical safety and performance (i.e. residual risks)**
- **PMCF** studies should be based on a PMCF plan (research protocol)
- Where PMCF as part of the PMS plan for the device is not deemed necessary, this must be justified by the manufacturer.

  NB will Assess the appropriateness of a justification where PMCF is not planned as part of the PMCF, and seek remedy where justification is not valid.
- **PMCF** can be instigated at any point in the post-marketing phase when **residual risks** are identified by PMS process
- **PMCF** study could be a **new clinical investigation.** However, it could also be:
  - The extended follow-up of patients enrolled in premarket investigations;
  - A review of data derived from a device registry; or
  - A review of relevant retrospective data from patients previously exposed to the device (retrospective studies)
- Where equivalence is claimed but the Clinical evaluation was in combination with either PMS or Clinical trials, the need for PMCF will depend on the relevance and weight given to the different data.

PMCF

PMCF is conducted on:

- Initial reviewed high-risk devices
- Where additional data is required for un-answered questions on residual risks.
- Borderline devices
- Devices where Literature was based on equivalent devices.
- Novel Devices
- new clinical claims, expanded conditions of use, changes in device characteristics, …
- Where PMCF is not planned and the justification is not valid.
- Where PMS identifies concerns on safety and performance.

—> see meddev 2.12 and FDA postmarked guidance

PMCF plan

- **PMCF plan** (MEDDEV 2.12/2 rev 2):
  - Clearly stated research question(s), objective(s) and related endpoints;
  - Identify the expected enrolment period, number of centres, number of devices to be used.
  - Scientifically sound design with an appropriate rationale and statistical analysis plan;
  - A plan for conduct according to the appropriate standard(s);
  - A plan for an analysis of the data and for drawing appropriate conclusion(s)

PMS report LVL Ophtalmo

- Scope : which devices, market analysis, how market , QT sold, how distributed, economic operators, world wide marketing approvals, similar devices - competitors, ….
- complaint / feed back analysis following your identified risks
- data on performance of your device (surveys, clinical data, literature, market related experience, exposure and use patterns, clinical trials similar devices ….
- trend reports
- feed back on product information (label , IFU, training, …
- data on any undesirable side effects, warnings, contra indications, safety signals, rare events, …
- Need for PMCF

Timing

The criteria for PMS, PMCF and Vigilance has increased and therefore manufactures need to demonstrate adequate

Pro-active gathering of data before a Notified Body will consider certification. This needs to start under MDD and not wait for MDR

Timing

new applications in the MDR (mid 2019)

lodge an application for assessment with

- - …
- The documentation on the manufacturer's post-market surveillance system and, where applicable, on the PMCF plan, and the procedures put in place to ensure compliance with the obligations resulting from the provisions on vigilance set out in Articles 87 to 92,
- a description of the procedures in place to keep up to date the post-market surveillance system, and, where applicable, the PMCF plan, and the procedures ensuring compliance with the obligations resulting from the provisions on vigilance set out in Articles 87 to 92, as well as the undertaking by the manufacturer to apply those procedures,
- documentation on the clinical evaluation plan, and
- a description of the procedures in place to keep up to date the clinical evaluation plan, taking into account the state of the art. 2.2.
- …

(Annxe IX - MDR)

You well need to be ready before applying a new CE certification assessment

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