Periodic Safety Update Report (PSUR)

Article 86

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Head of Clinical Compliance

29th September 2021

By Royal Charter

bsi.

Disclaimer

What is presented today is based on our current knowledge and interpretation.

Poll Question

In relation to the PSUR, which parts of the MDR are relevant?

- Article 83, 84, 86, 87, 88 and 89
- Article 120 (3)
- Annex III & Annex XIV
- All of the above

Poll Answer

In relation to the PSUR, which parts of the MDR are relevant?

- Article 83, 84, 86, 87, 88 and 89
- Article 120 (3)
- Annex III & Annex XIV
- All of the above

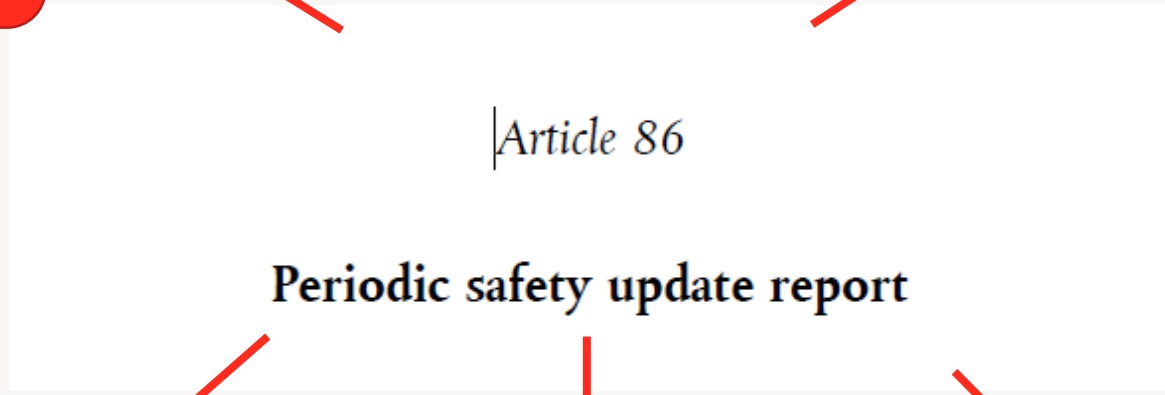
The Requirements

Article 86 should not be considered alone when in view of the PSUR and its Impact.

Article 83 = PMS System
Article 84 = PMS Plan

Article 120 (3)

MDD 93/42/EEC
AIMDD 90/385/EEC



Article 86

Periodic safety update report

Annex III
PMS Activities
Reactive & Proactive

Annex XIV
Part B - PMCF

Article 87= Vigilance
Article 88 = Trend Reports
Article 89 = FSCA

Article 86

- Article 86 requires manufacturers of Class IIa, IIb, III devices to prepare a PSUR
- Output of PMS activities of Annex III form the basis of the PSUR

Article 86

Periodic safety update report

1. Manufacturers of class IIa, class IIb and class III devices shall prepare a periodic safety update report ('PSUR') for each device and where relevant for each category or group of devices summarising 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. Throughout the lifetime of the device concerned, that PSUR shall set out:

(a) the conclusions of the benefit-risk determination;

(b) the main findings of the PMCF; and

(c) the volume of sales of the device and an estimate evaluation of the size and other characteristics of the population using the device and, where practicable, the usage frequency of the device.

Manufacturers of class IIb and class III devices shall update the PSUR at least annually. That PSUR shall, except in the case of custom-made devices, be part of the technical documentation as specified in Annexes II and III.

Manufacturers of class IIa devices shall update the PSUR when necessary and at least every two years. That PSUR shall, except in the case of custom-made devices, be part of the technical documentation as specified in Annexes II and III.

For custom-made devices, the PSUR shall be part of the documentation referred to in Section 2 of Annex XIII.

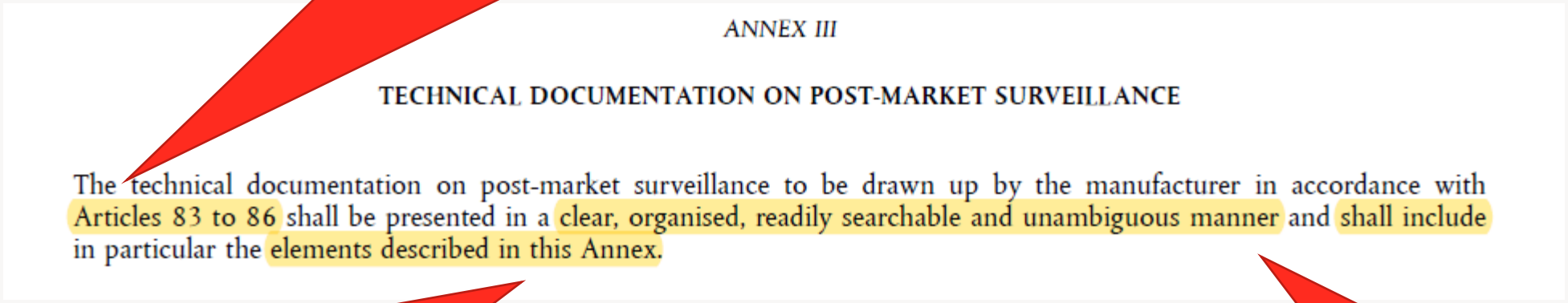
2. For class III devices or implantable devices, manufacturers shall submit PSURs by means of the electronic system referred to in Article 92 to the notified body involved in the conformity assessment in accordance with Article 52. The notified body shall review the report and add its evaluation to that electronic system with details of any action taken. Such PSURs and the evaluation by the notified body shall be made available to competent authorities through that electronic system.

3. For devices other than those referred to in paragraph 2, manufacturers shall make PSURs available to the notified body involved in the conformity assessment and, upon request, to competent authorities.

Class I devices are required to prepare a Post Market Surveillance report per Article 85

Annex III

Articles 83-86
Article 83 = Post Market Surveillance System of the Manufacturer
Article 84 = Post Market Surveillance Plan
Article 85 = Post Market Surveillance Report (Class 1 Only)
Article 86 = Periodic Safety Update Report (PSUR) (Class IIa, IIb, III)



ANNEX III

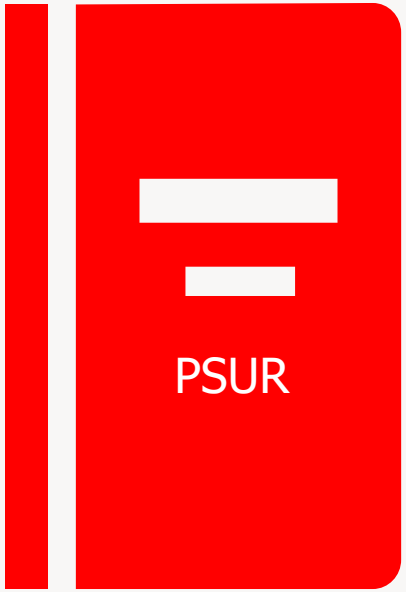
TECHNICAL DOCUMENTATION ON POST-MARKET SURVEILLANCE

The technical documentation on post-market surveillance to be drawn up by the manufacturer in accordance with Articles 83 to 86 shall be presented in a clear, organised, readily searchable and unambiguous manner and shall include in particular the elements described in this Annex.

Section 1.1.a = Types of Data Collection
Section 1.1.b = The 'Proactive and Reactive' Methods of Collection
Section 1.2 = Connection of activities in relation to reporting within the PSUR

- PDF Document
- MDCG Template to be provided and followed

PSUR



The Manufacturer's PSUR…

- ✓ Is a snapshot of PMS data at a set time point
- ✓ Should accurately reflect the output of the PMS Plan
- ✓ Should confirm if the benefit/risk is impacted by the data
- ✓ Should demonstrate sufficient evidence of a well integrated Risk Management, Clinical Evaluation and Post Market Surveillance Process

The Notified Body's PSUR Evaluation…

- ✓ Should confirm the output of activities of the PMS Plan have been captured
- ✓ Should confirm the adequacy of the data, identifying any anomalies/concerns
- ✓ Should conclude whether the manufacturers benefit/risk statement is appropriate based on the data within the PSUR
- ✓ A separate evaluation report is only required for Class III and Implantable Devices

The Periodic Safety Update Report (PSUR)

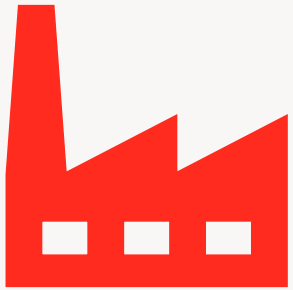
The aim of the PSUR is not to duplicate all data and reports generated by the PMS Plan: it should summarize all results and conclusions generated after the implementation of Post Market Surveillance Plan.

The PSUR can point to other documentation such as detailed vigilance reports, Post Market Clinical Follow-up (PMCF) Evaluation Reports, etc. but the PSUR must contain sufficient detail to allow for independent assessment and conclusions to be drawn.

In view of facilitating consistency and readiness for Notified Bodies and Competent Authorities between the PSURs of the same manufacturer and between manufacturers, it is recommended that, to the extent possible, the same structure is followed for the drafting of all PSUR reports regardless of the device class. *i.e. follow the provided template.*

Actors Involved Within the PSUR

Manufacturers



Manufacturers will

- Prepare PSUR in accordance to the Guidance*
- Submit PSUR to EUDAMED For Class III and Implantable Devices
- Make PSUR Available to Notified Body for Class IIa/IIb Non Implantable devices as part of Surveillance

Notified Bodies

Notified Bodies will

- Perform an evaluation of the PSUR for all Class III and implantable devices and upload an evaluation of the PSUR to EUDAMED
- Perform an evaluation of the PSUR for all Class IIb and IIa non-implantable devices as part of TF Sampling/Surveillance

National Competent Authorities

Competent Authorities may

- Request PSURs/NB Evaluations as part of vigilance activities, clinical investigation reviews and part of other market surveillance activities.

**Other economic operators (authorised representatives, distributors, importers) must assist the manufacturer in contributing & gathering the necessary information*

Visibility of the PSUR in EUDAMED

- All Competent Authorities can view all PSURs
- Manufacturers can only view their own PSURs
- Notified Bodies can only view PSURs for the certi

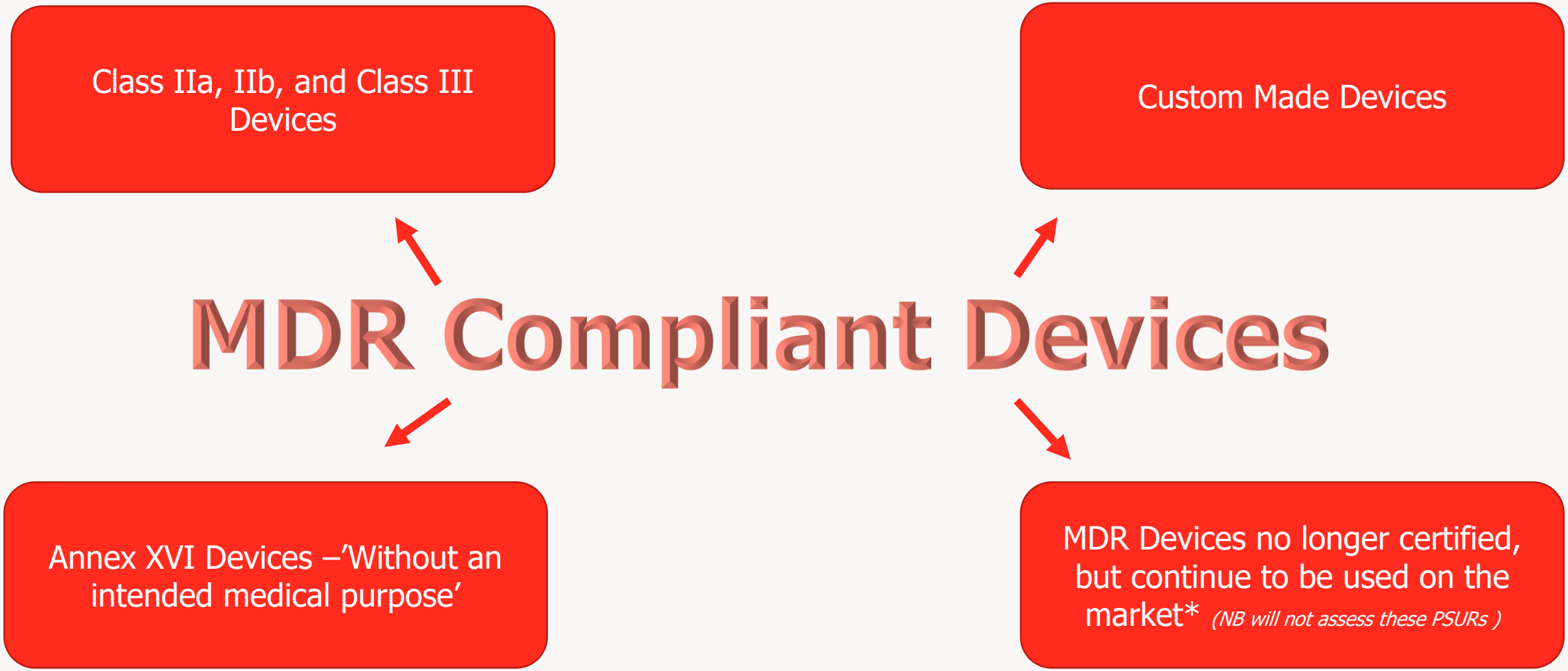
PSURs will not be made public.

Of course certain types of data e.g. PMCF may end up in the SS(C)P which is a public document

- All Competent Authorities can view all PSUR Evaluations
- Manufacturers can only view their own PSUR Evaluations
- Notified Bodies can only view PSUR Evaluations for the certificates they issue

PSUR Evaluations will not be made public.

Devices in the Scope of the PSUR



*Unless the manufacturer has ceased business or bankruptcy.

What about Legacy devices?

'

I only currently hold a MDD Certificate do I need to also prepare a PSUR?'

YES!

Article 120 (3)

The requirements of this Regulation relating to post-market surveillance, market surveillance, vigilance, registration of economic operators and of devices shall apply in place of the corresponding requirements in those Directives.

This includes the requirement to produce a PSUR for devices continued to be certified and placed on the market under AIMDD 90/385/EEC and MDD 93/42/EEC until

26th May 2024

Devices in the Scope of the PSUR

Class IIa, IIb, and Class III Devices with a valid certificate

Custom Made Legacy Devices

MDD/AIMDD Compliant Devices

NOTE: Devices which are placed on the market under the MDD/AIMDD before the MDR Date of Application (DoA) and which are **NOT** continued to be placed on the market after DoA (so called "old devices") are not covered by the MDR, thus the obligation of the PSUR does not apply to them. However the manufacturer must continue to perform the PMS as specified in the MDD (93/42/EEC annex X 1.1c)/AIMDD (90/385/EEC annex 5, 4.) for these devices.

Legacy Device PSUR

- Notified bodies will ensure that manufacturers have procedures in place for the generation of a PSUR as part of general surveillance activities.
- Notified bodies will not assess every PSUR for legacy devices but manufacturers should make them available upon request.
- Notified bodies may request PSURs (if available) as part of your initial conformity assessment to MDR

This is our current understanding and we expect information to be released by the Commission.

Poll Question

Which Classification of device is the Notified Body's evaluation required to be uploaded to EUDAMED?

- Class IIa/IIb Implantable & Class III/Class
- Class III/C Only
- All Classifications

Poll Answer

Which Classification of device is the Notified Body's evaluation required to be uploaded to Eudamed?

- Class IIa/IIb Implantable & Class III/Class
- Class III/C Only
- All Classifications

PSUR & Classification

Classification	Minimum Frequency of PSUR Report	Manufacturer Uploads to Eudamed?	Notified Body Evaluation Report?
Class III	Annual	Yes within 90 days	Yes -Within 90 days and uploaded to EUDAMED
Class IIb Implantable	Annual	Yes within 90 days	Yes - Within 90 days and uploaded to EUDAMED
Class IIb Non -Implantable	Annual	No	Completed as part of Technical File Surveillance
Class IIa Implantable	Biennial	Yes within 90 days	Yes - Within 90 days and uploaded to EUDAMED
Class IIa Non-Implantable	Biennial	No	Completed as part of Technical File Surveillance

Class I Medical Devices need to prepare a PMS Report NOT a PSUR.

Submission Times

Class III and Implantable Devices

Subject to EUDAMED

12/24* Month Manufacturer's Data Collection

Manufacturers will collect the data over the set period of time based on classification

Manufacturers will have 90 calendar days to prepare the data into a PSUR and submit to EUDAMED

90 day Preparation Time

Once uploaded to EUDAMED, the NB will Evaluate the contents and upload its Evaluation report to EUDAMED within 90 calendar days. In exceptional cases this maybe 180 calendar days.

90 day NB Evaluation

*Data Collection Period is 24 months for implantable Class IIa devices.

If devices are added to the certificate at a later date the PSUR submission date remains unchanged. It is accepted that there may be shorter data sets for those devices for the first reporting period.

Custom Made Devices.

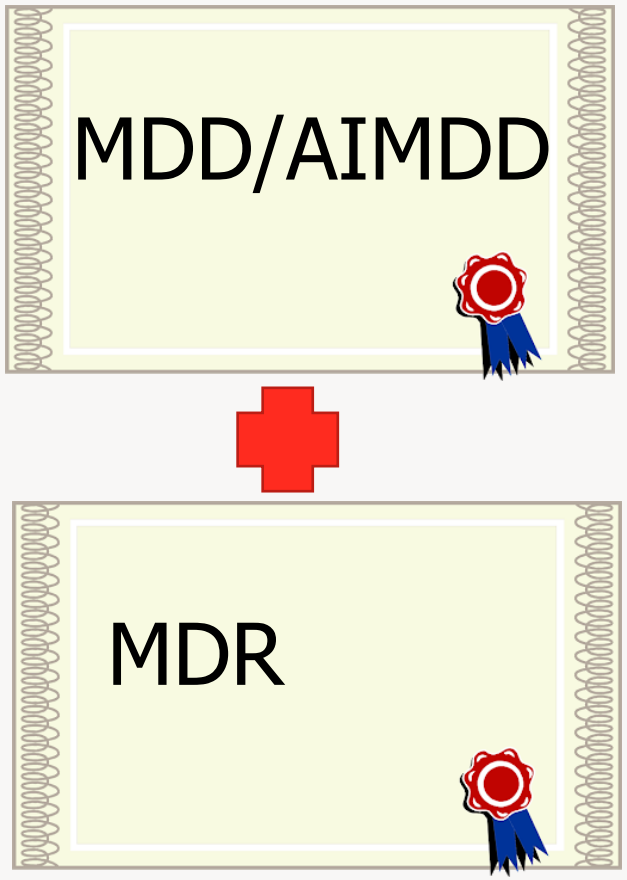
FREQUENCY:
PSUR to be generated per classification requirements in MDR.

EUDAMED:
Not required to be uploaded to EUDAMED.

AVAILABILITY:
To be made available to Competent Authorities and Notified Body upon request

NOTIFIED BODY EVALUATION:
Evaluation to be performed as part of Renewals/other activities.

Devices on both MDR and MDD/AIMDD Certificates



There is an allowance for the same devices on both MDD/MDR certificates to be reported in one PSUR, however it must be clear from the presented data which devices that were placed on the market under MDD or MDR

PSUR

MDD Devices = 336 units

MDR Devices = 432 units

Analysis of **all** data should be considered – But be careful there may be some differences between MDD/AIMDD certified devices and MDR certified devices.

MDCG Guidance

- We are expecting the guidance to be released by the end of the year.
- We are expecting information on requirements of the PSUR for legacy devices to be released prior the guidance.
- The MDCG Guidance is expected to provide a template and information for manufacturers to follow including templates on data sets is expected to be included.
- Per Annex III, it is **critical** manufacturers follow the template provided

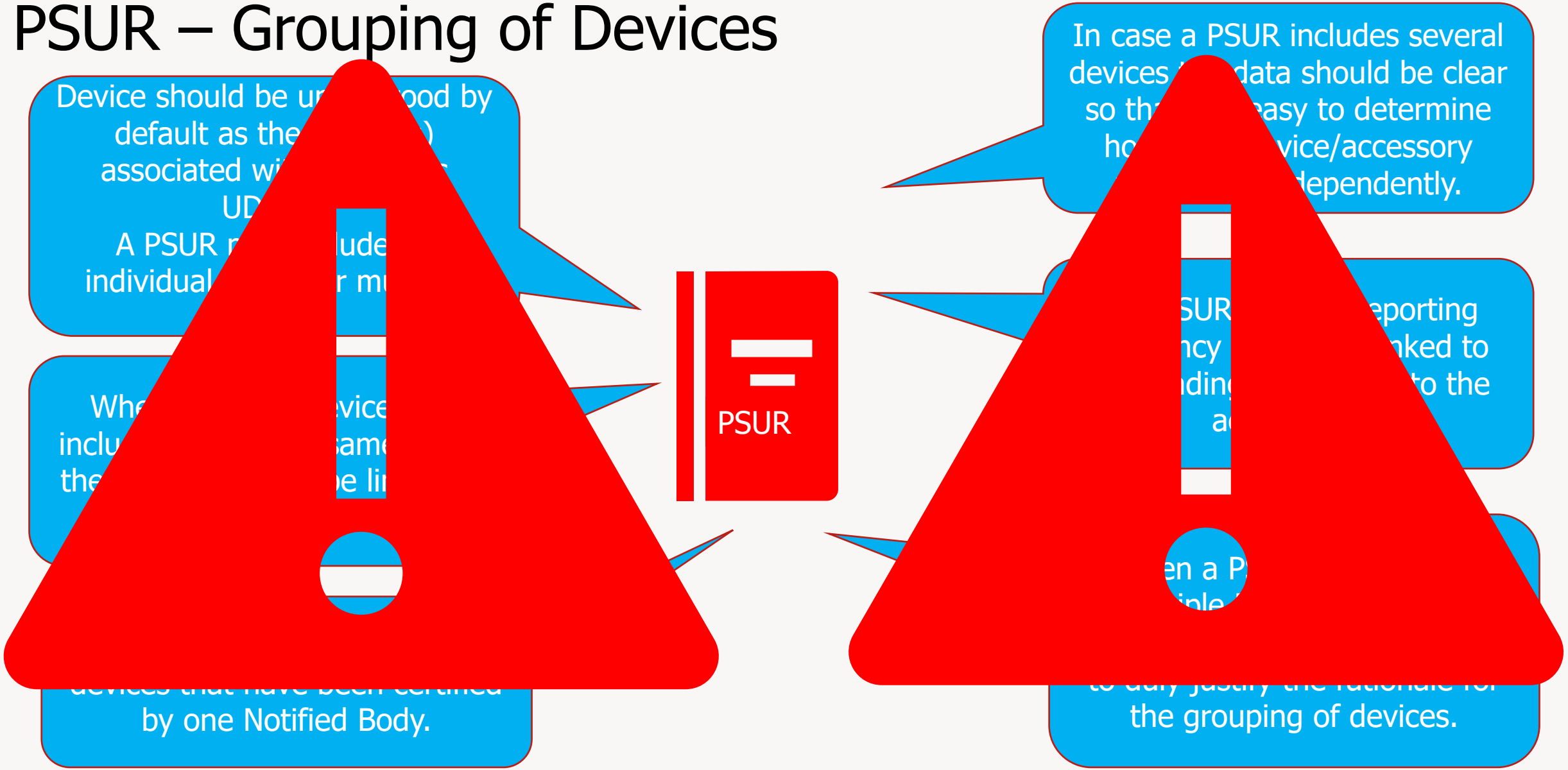
Dat

Manufacturers should get used to using the IMDRF codes in categorising the device failure modes, patient effects etc. These coding systems are going to be a mainstay of the future.

Other Considerations when Presenting Data in the PSUR

- Data collected should highlight unfavourable as well as favourable conclusions.
- Data should be comparable between generations of devices.
- IMDRF Codes to level 2 should be used when possible;
  - ***Device problem code (Annex A)***
  - ***Health impact code (Annex F)***
  - ***Investigation finding code (Annex C)***

PSUR – Grouping of Devices



Exceptions to the rules may be permitted on agreement with the notified body, but must be appropriately justified.

When should I start collecting data for my PSUR?

Legacy Devices

May 26th 2021

1st PSUR

PSURs for legacy devices do not need to contain PMS data prior to May 26th 2021, but can reference previous years PMS reports, this data should be considered in conjunction with the analysis of the current PMS data within the conclusions of the PSUR.

When should I start collecting data for my PSUR?

MDR Certified Devices

MDR Certificate Issue Date or Declaration of Conformity

1st PSUR

Executive Summary, Description of Devices, Justification of Grouping.

Executive Summary – *An executive summary should be sufficient to provide conclusions from previous PSURs and any actions taken, along with main results of the current PSUR* ***with*** *a clear statement declaring whether the data obtained and presented in the current PSUR has impacted the benefit/risk of the device.*

Description of Devices – *A sufficient description of devices should be provided with all appropriate regulatory information and history. (Alignment with the device description in MDCG 2019-9)*

Justification of Grouping of Devices – *If data from multiple Basic-UDI-Dis are being presented in the PSUR, a justification should be provided as to why it is acceptable to group additional devices.*

Presentation of Data

- **Volume of sales/usage**
  - Data should be presented based on size, model configurations etc.
  - Justification should be provided as to the method used.

- **Characteristics of the population using the devices(s)**
  - May not always be possible to have this data - Justification should be provided
  - Consider any off label use as evidence towards where it is being used.
  - Consider changes in patient populations with other emerging technologies/therapies

- **Vigilance Data**
  - Vigilance data including possible detected signals/trend reports (Articles 87 & 88)
  - Preventive and Corrective Actions (Article 83.4)
  - FSCAs (Article 87)

Annex III calls out these activities and these should be reported and reflected per the Manufacturers PMS Plan

Post Market Surveillance (PMS) Data & General PMCF

❑ Feedback and Complaints

- Most Significant Complaints should be reported with a justification for those not considered significant.
- Complaints that initiated CAPAs

❑ Literature Searches

- Overview of literature searches conducted
- Identify any new or emerging concerns

❑ Public Registry Data

- Overview of registry data collections conducted
- Identify any new or emerging concerns

❑ Publicly Available Information about Similar Devices

- Source of information identified
- Similar = shared 'Common Intended Purpose' (Article 2 (7))
- Identify any new or emerging concerns for this generic group

❑ Other Data Sources

- Consider other Real World Evidence
- Name source

Specific PMCF Activities

The main findings of PMCF should be presented per Article 86 (1) (b)

The information should highlight the progress of the activities and whether there have been any deviations of protocol, or new risk identified

This should include not only PMCF studies but also other specific methods of PMCF conducted by the Manufacturer.

Notified bodies will evaluate the progression and conclusions of agreed PMCF Activities

Conclusions of PMCF should be evident within the PSUR with allowance to reference the PMCF evaluation report for a more comprehensive assessment

PMCF Study Data

- Name & Type of PMCF Activity,
- Start date of PMCF Activity, and planned end date of PMCF activity,
- Number of total enrolled participants Vs number of planned participants per PMCF plan,
- Number of total enrolled sites Vs number of planned sites per PMCF plan,
- Any new risks or direct patient harm identified from PMCF activities,
- Any study protocol deviations or issues identified hindering the conduct of PMCF activity
- Any change in relation to state of the art identified from PMCF activity

Is the PMCF on Track? Are there any concerns?

It is acceptable for the manufacturer to point to their PMCF Evaluation Report for Further Information (MDCG 2020-8)

Summary of the Collected Data

A Summary should be provided of all collected data.

- ✓ Provide an overview of the data collected with reference to its adequacy and quality,
- ✓ The summary should highlight any possible deficiencies and bias of the collected data
- ✓ Whether the collected data is sufficient to draw conclusions on safety/performance

The Conclusions of the Manufacturer

Conclusions of Risks

- Confirm if risks remain the same and within the agreed risk management profile for the device
- Have new risks been introduced from collected data?
  - Do these risk impact a specific size of device/patient population?
  - What is the occurrence /severity of the risk?
  - Is this is a regional risk?
  - Rationale for acceptability of risk?
  - What actions have taken place to reduce risk?

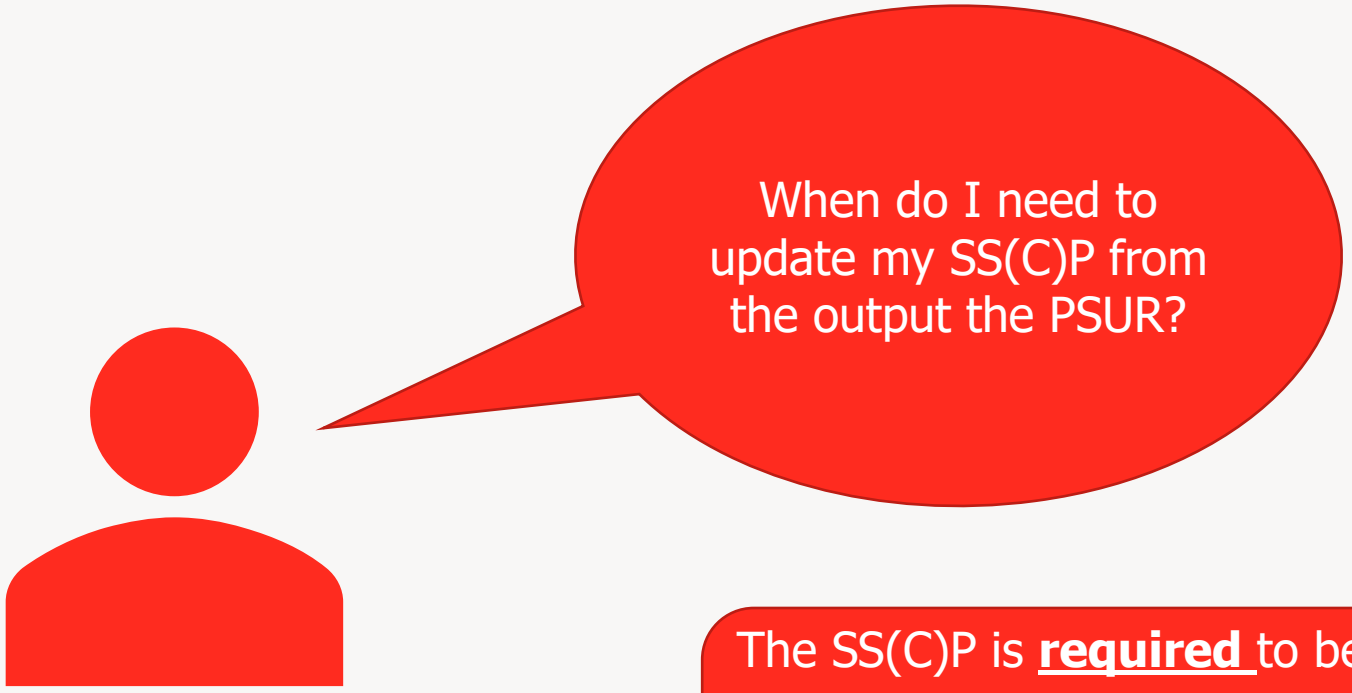
Conclusions of Benefits

- Confirm if the benefit profile of the device remains as originally intended.
- Identify any adverse impact to benefit

Overall Conclusions & Impact

- ✓ Provide an overall conclusion of the data collected in relation to the benefit/risk profile
- ✓ Provide a statement of whether the benefit/risk profile has been adversely impacted by the data collected (*align with Executive Summary*)
- ✓ Provide a list of corrective measures generated from the current PSUR
- ✓ Describe essential changes to the PMS plan
- ✓ Confirm updates are required for SSCPs – (Class III and Implantable)
- ✓ Identify specific considerations for the next PSUR update.

PSUR - *Updates to SSCP /SSP*



The SS(C)P is **required** to be updated if…..

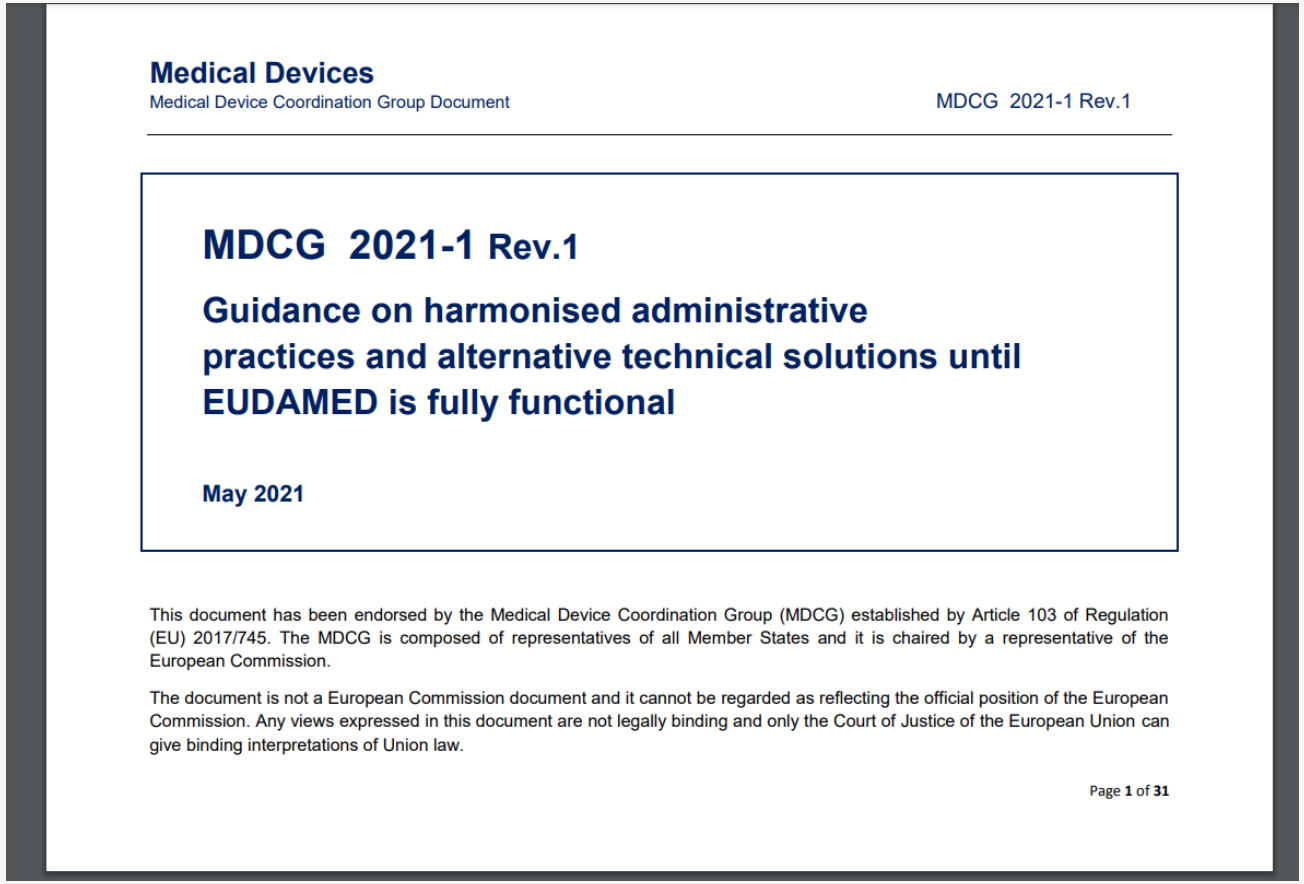
any PMS activity that renders the information in the SSCP invalid.

Refer to MDCG 2019-9 for further information.

MDCG 2021-1 (rev 1)

In the absence of EUDAMED…

- PSURs will need to be submitted direct to the Notified Body. **(MDR Devices Only)** :
- Notified Bodies are required to provide evaluations direct to the Manufacturer.



Medical Devices
Medical Device Coordination Group Document

MDCG 2021-1 Rev.1

MDCG 2021-1 Rev.1

Guidance on harmonised administrative practices and alternative technical solutions until EUDAMED is fully functional

May 2021

This document has been endorsed by the Medical Device Coordination Group (MDCG) established by Article 103 of Regulation (EU) 2017/745. The MDCG is composed of representatives of all Member States and it is chaired by a representative of the European Commission.

The document is not a European Commission document and it cannot be regarded as reflecting the official position of the European Commission. Any views expressed in this document are not legally binding and only the Court of Justice of the European Union can give binding interpretations of Union law.

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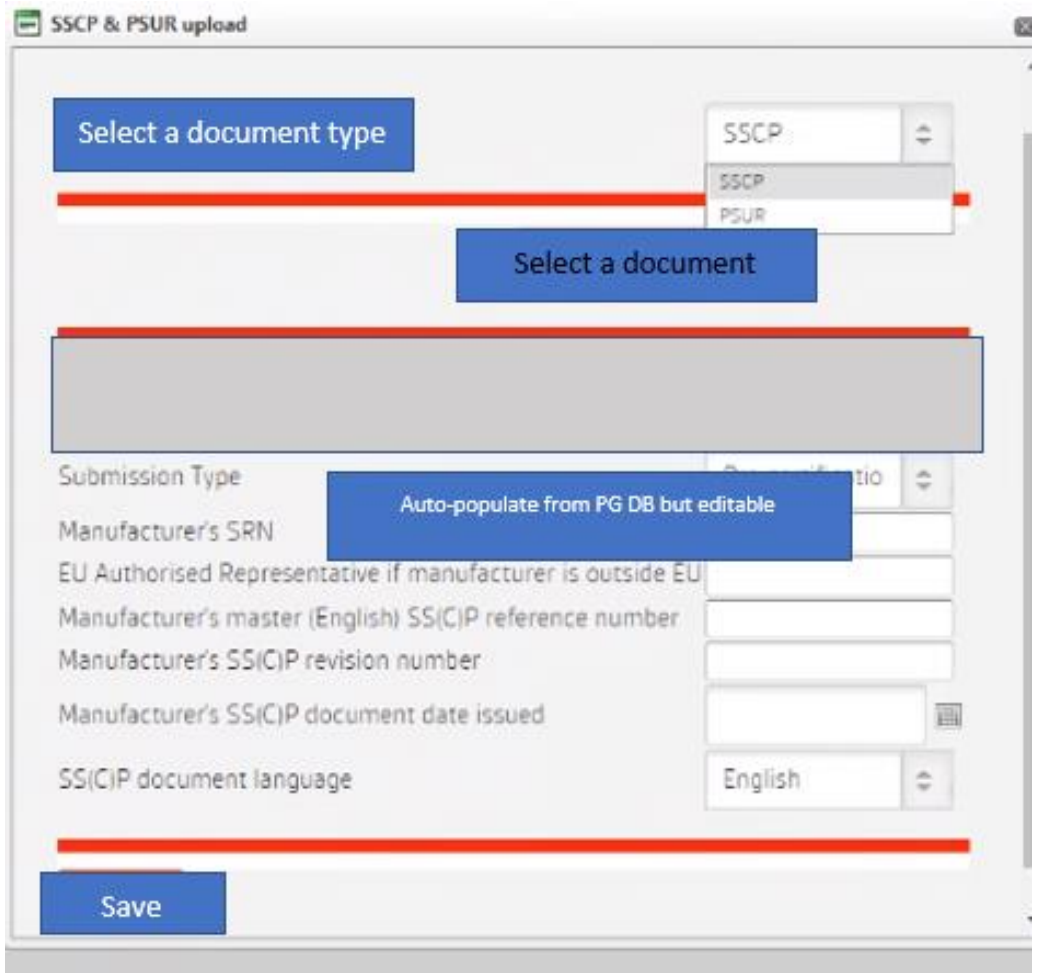
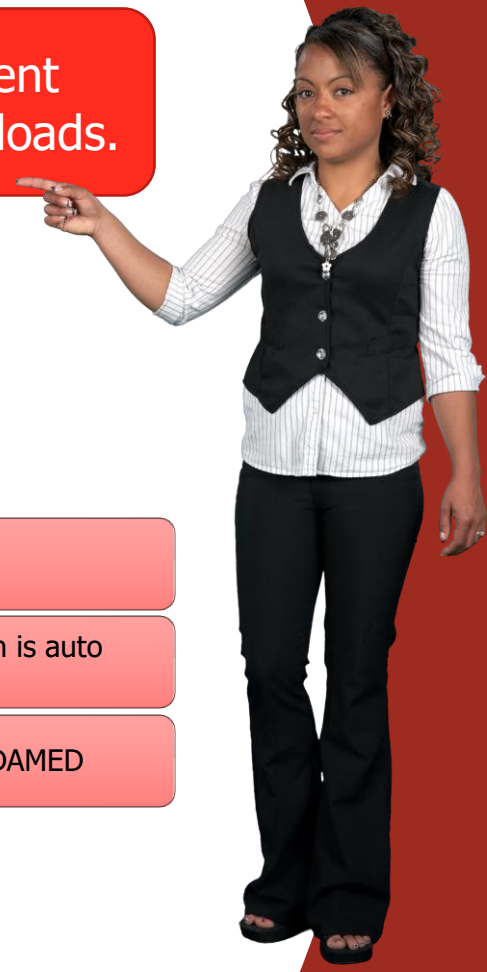
Client Portal Changes



BSI will provide full instructions in a client communication to assist you with your uploads.



Choose the type of document- PSUR or SS(C)P

Metadata to be filled in by manufacturer apart from SRN which is auto populated

Language list will include all European Languages as per EUDAMED

Vigilance and Trend Reporting

Articles 87 and 88

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29 Sept, 2021

By Royal Charter

bsi.

Scope

Will cover:

- What a vigilance event is.
- When it is reportable.
- A comparison of requirements under MDD and MDR.
- Any new or enhanced requirements.

Will not cover:

- The detailed reporting responsibilities and technicalities under MDD / MDR.
- FSCAs

References

BSI – White Papers

https://www.bsigroup.com/en-GB/medical-devices/resources/whitepapers/

- Responsibilities for medical device vigilance reporting (MDR)
- Post-market surveillance under the MDR/IVDR

MDD

- MDD (or AIMD) Annex II(2) 3.1
- Meddev 2.12 rev 8 (Jan 2013)

MDR

- Annex IX 2.1 (e.g.)
- Articles 87-92, in particular:
  - Article 87 - Vigilance
  - Article 88 – Trend Reporting.
- 2 MDCG Q&A documents… TBD

MDD / MDR requirement for vigilance

MDR

Annex IX * 2.1 Quality System, … 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**,

MDD

- Annex II * 3.1 Quality System, … an obligation for the manufacturer to notify the competent authorities of the following incidents immediately on learning of them:
  - **(i) any malfunction or deterioration in the characteristics and/or performance of a device, as well as any inadequacy in the instructions for use which might lead to or might have led to the death of a patient or user or to a serious deterioration in his state of health;**

* Other routes to conformity are available.

Identifying a Vigilance Event

MDR Article 87

Article 2 **Definitions**

(65) '**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, …

Article 87 **Reporting of serious incidents and field safety corrective actions**

1.Manufacturers of devices made available on the Union market, other than investigational devices, shall report, to the relevant competent authorities, in accordance with Articles 92(5) and (7), the following:

(a) any **serious incident** involving devices made available on the Union market**,** except expected side-effects which are clearly documented in the product information and quantified in the technical documentation and are subject to trend reporting pursuant to Article 88;

(b) Any FSCAs …

Meddev 2.12 Rev 8 Section 5.1.1

A. An event has occurred: **Typically** a malfunction or deterioration in performance according to the manufacturer's instructions.

B. Manufacturer's device is suspected to have contributed to the incident.

C. The event led *, or might have led to **Death** or serious deterioration in health. **Can include** **
   - **a) life threatening illness**,
   - **b) permanent** impairment of body function or **permanent** damage to body structure, OR a
   - c) condition necessitating medical or surgical intervention to prevent a) or b).

* Meddev omits future tense … "Might lead to", but it is still in MDD An II 3.1.

** Manufacturers sometimes use this as a definitive list, rather than just some examples, & fail to relate guidance to own device.

Reporting Deadlines

MDR Article 87

4. in the event of a **serious public health threat** … not later than **2 days**

5. in the event of **death or an unanticipated serious deterioration in a person's state of health** … not later than **10 days**…

3.Manufacturers shall report **any serious incident** … immediately after they have established … causal relationship is reasonably possible **and not later than 15** days after they become aware of the incident.

7.If, … the manufacturer is **uncertain** about whether the incident is reportable, **it shall nevertheless submit a report** within the timeframe …

6. … to ensure timely reporting, the manufacturer may submit an initial report … followed up by a complete report.

Meddev 2.12 Rev 8 Section 5.1.7

Serious public health threat: IMMEDIATELY … not later than **2 calendar days** after awareness by the MANUFACTURER of this threat.

Death or UNANTICIPATED serious deterioration in state of health: IMMEDIATELY …not later than **10 calendar days** following the date of awareness of the event.

Others: IMMEDIATELY . **30 elapsed calendar days** following the date of awareness of the event

If after becoming aware of a potentially reportable INCIDENT **there is still uncertainty** about whether the event is reportable, the MANUFACTURER must **submit a report within the timeframe** required for that type of INCIDENT.

Periodic Reporting

MDR Article 87

- 9. Similar serious incidents, same device or device type, root cause has been identified, or FSCA implemented, or incidents are common and well documented …..
- With agreement from Competent Authority referred to in Art 89(9), in consultation with Competent Authorities in Art 92(8)(a)…
- Format, content and frequency agreed….
- May provide summary reports following agreement with Competent Authority in Art 92(8) (a) and (b) …

Meddev 2.12 Rev 8

- 5.1.2 Periodic Summary Reporting, for certain types of incident,
- with agreement from Competent Authority.
- Other Competent Authorities shall be informed, and
- can only extended to other Competent Authorities on agreement.

Trend Reporting

MDR Article 88	Meddev 2.12 – 1 rev 8 Section 5.1. 4
To the **electronic system** referred to in Article 92	To the relevant **Competent Authority** (place of manufacturer or Authorised rep)
Any **Statistically Significant** increase in Frequency or Severity of Incidents	**Significant** increase or trend of events or INCIDENTs
That are **not serious incidents**, **OR are expected undesirable side effects**.	**Excluded by 5.1.3** (a list of possible exclusions including Expected and foreseeable side effects 5.1.3.5)
Shall **specify how to manage incidents, and methodology for determining statistically significant increase … in the PMS Plan, ref Article 84**	Suitable systems to detect trends.

Not in MDR: Examples

- Vigilance events covering a range of device types and scenarios.
- Possible exclusions : e.g. Meddev 2.12R8: 5.1.3.1 Deficiency found prior to use, 5.1.3.2 Event Caused by Patient Conditions, 5.1.3.3 DEFINED Service / shelf life exceeded, 5.1.3.4 Protection of a fault functioned correctly, **5.1.3.5 Expected and foreseeable side effects,** 5.1.3.6 Negligible likelihood of occurrence of death or serious injury.
- Around the changes e.g. “directly or indirectly led” or “temporary or permanent” serious deterioration of person’s health…

Expected in MDCG Q&A guidance (TBD…)

Poll Question

Loosening of a recently released replacement hip joint shortly after implant, is reported to manufacturer. It is inconclusive as to whether it is device failure. Device not yet explanted or returned so manufacturer cannot perform investigation. Is this reportable as a vigilance event?

A) No
B) Under MDR Only
C) Under MDR and MDD.
D) It depends. (reason in comments)

Poll Answer

Loosening of a recently released replacement hip joint shortly after implant, is reported to manufacturer. It is inconclusive as to whether it is device failure. Device not yet explanted or returned so manufacturer cannot perform investigation. Is this reportable as a vigilance event?

C) Under MDR and MDD.

Meddev 2.12 Rev 8 Section 5.1.7., MDR Article 87 7.,

If the manufacturer is uncertain … it shall nevertheless submit a report

Poll Question

Chronically implanted device, claimed patient benefit to improve Quality of Life, not life / ability - sustaining, fails prior to defined / expected lifetime such that the benefit of the implant is lost. Is this reportable as a vigilance event?

A) No
B) Under MDR Only
C) Under MDR and MDD.
D) It depends. (reason in comments)

Poll Answer

Chronically implanted device, claimed patient benefit to improve Quality of Life, not life / ability - sustaining, fails prior to defined / expected lifetime such that the benefit of the implant is lost. Is this reportable as a vigilance event?

C) Under MDR and MDD.

MDD Annex II * 3.1 , MDR Article 2 (65)
"might lead to or might have led to ….", "directly or **indirectly led…"** (MDR)

It may have been evaluated under MDD that failure would not lead to injury/death.
However this does not consider the *indirect* risks the patient will have to undergo due to failure.
Risks to the patient associated with implantation, explantation, or revision surgery MUST be taken into account.
MDR is a clarification of this point.

Conclusion - Has anything changed?

- **Yes** – some new terms, tightening of definitions, reduced time to report, way to report, it's in the MDR and not just guidance. More focus on trend reporting.
- **No** – Despite changes in definitions etc., Few events previously unreportable may now be reportable.

Movement into MDR = more scrutiny of the vigilance and related processes. May lead to nonconformities for those who haven't fully considered impact.

(Also note, for BSI clients, the reporting obligations within the contract.)

Addendum …

- Commission is working on a new MIR, FSCA/FSN forms, templates and Periodic Summary Report form. There is also an NCAR form being worked on for the CAs to use. All updates to these forms/templates to meet the new MDR/IVDR reporting requirements

- Many manufacturers are still using MIR version 7.2 or lower to report currently, although they should have been using version 7.2.1 since 01 Jan 2021. Please use form version 7.2.1.

- Manufacturers should get used to using the IMDRF codes in categorising the device failure modes, patient effects etc. These coding systems are going to be a mainstay of the future.

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Brochures, Guides and Documents

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White Papers and Articles

Person responsible for regulatory compliance (PRRC) - MDR/IVDR Article 15

With the MDR and IVDR, European regulators aim to ensure companies have a regulatory expert – a Person Responsible for Regulatory Compliance (PRRC) – at their disposal, to ensure that the company is meeting certain specific EU requirements.

Software as a medical device - A comparison of the EU's approach with the US's approach

The International Medical Device Regulators Forum (IMDRF) aims to accelerate international medical device regulatory convergence. Through the IMDRF, regulators reached consensus on what software is considered a medical device. Regulators call it 'software as a medical device' (SaMD). This paper provides a comparison of how SaMD is regulated in the US and in the EU.

Machine learning AI in medical devices

How is AI different from traditional medical devices and medical software and what are the implications of those differences? What controls are necessary to ensure AI in healthcare is safe and effective?

Medical device clinical investigations – What's new under the MDR?

The conduct of a clinical investigation is one of the most time consuming and resource intensive activities that a medical device manufacturer can face. This paper discusses important new requirements for pre-market and post-market clinical investigations under the European MDR.

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Thank you for joining today

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