Post-market surveillance and vigilance (PMSV)

Seminar 2024-06-19 Kista/Stockholm

Labquality at a Glance

LABQUALITY

150 Staff

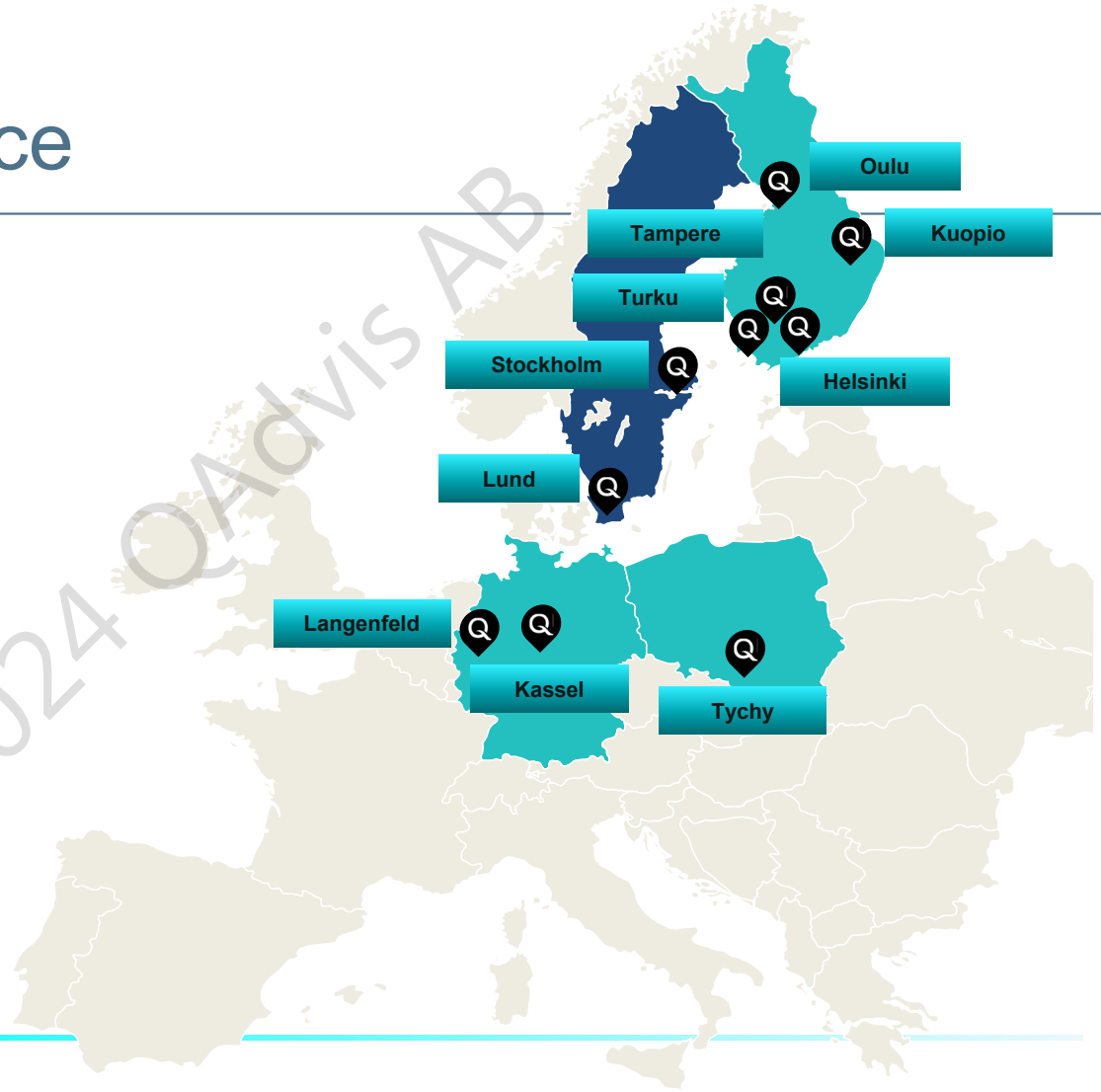
17M€ Revenue

60+ Countries

400 direct customers

40+ distributors

8000 customers via distributors



Labquality in a Nutshell

Clinical Laboratories

- **EQA - external quality assessment**
- **Reference samples for validation**
- **In-house methods and training**

Medical Devices & *In Vitro* Diagnostics

- **Regulatory affairs & CRO services**
  - ✓ Global registrations for devices and software
  - ✓ Technical documentation
  - ✓ Quality management systems (QMS)
  - ✓ Validation and verification services
  - ✓ Clinical investigations (CRO)
  - ✓ Digital health QA/RA, development and platform services

Pharmaceuticals & Biotech

- **Clinical trial services (CRO)**
- **Pre-clinical research**
- **Regulatory affairs**

Social and Healthcare

- **Certification services**
  ISO 9001, SFS-EN 15224, ISO 14001, ISO 27001
- **SHQS Quality program**
- **Clinical site audits**

Digital Services

- ✓ LabScala
- ✓ Direct integration to LIMS
- ✓ Entries

Labquality | PRO

- ✓ Training:
  - Live
  - Virtual
  - On-Demand
- ✓ Labquality Days
- ✓ PocT training

Presentation of the speaker – Marie Mathiasson

- Quality and Regulatory Consultant at QAdvis
- Analytical chemist at Uppsala University
- Laboratory Analyst and assessor/Inspector at MPA
- 13+ years at Swedish MPA in the Medical Device Department

PMS SYSTEM & VIGILANCE

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Regulations Demands

- Development
- Design
- Verification
- Labeling
- Production
- Documentation
- **Traceability**
- **Market Availability**

Manufacturers must **proactively** and **reactively monitor** product use. They must also **track technical** and **scientific advancements** for product relevancy. Monitoring ensures products maintain **safety** and **performance**.

Post-market Surveillance's definition

Definition of PMS according to EU MDR Art. 2(60) and IVDR Art. 2(63):

„all activities carried out by the 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 their devices placed on the market, made available or put into service for the purpose of identifying any need to immediately apply any necessary corrective or preventive actions"

Post-market surveillance

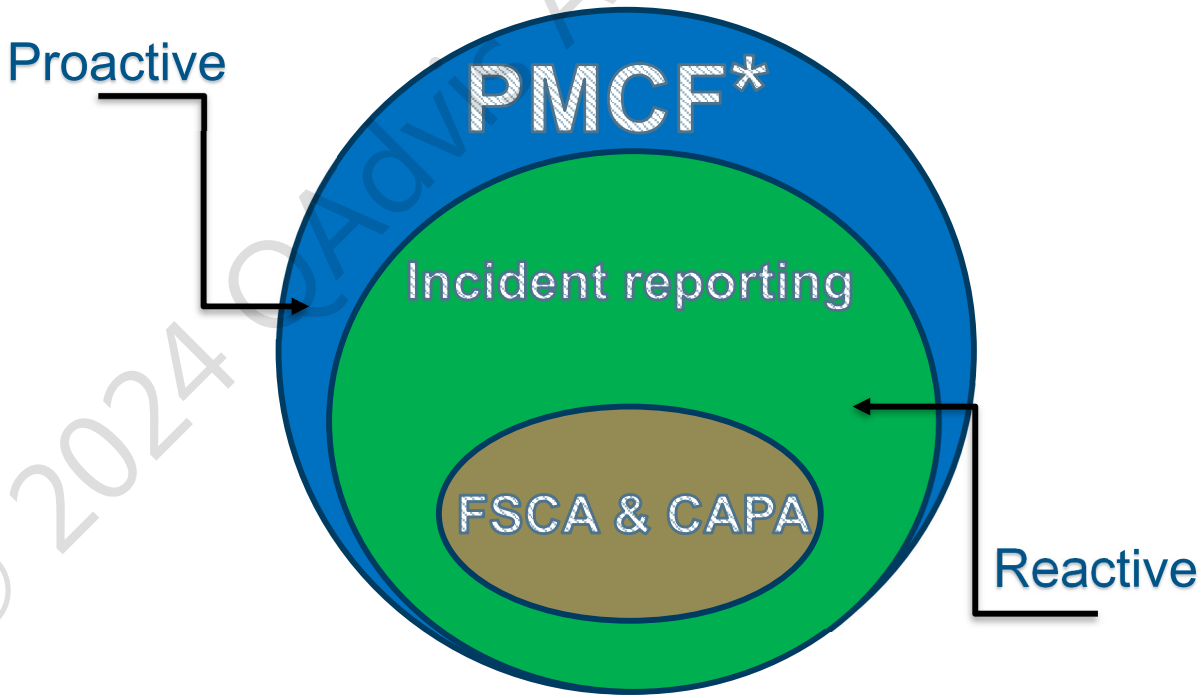
Potential Sources

Proactive:

- Literature
- Database and/or registries
- Feedback and complaints (users, distributors, importers)
- Publicly available information on similar devices (globally)

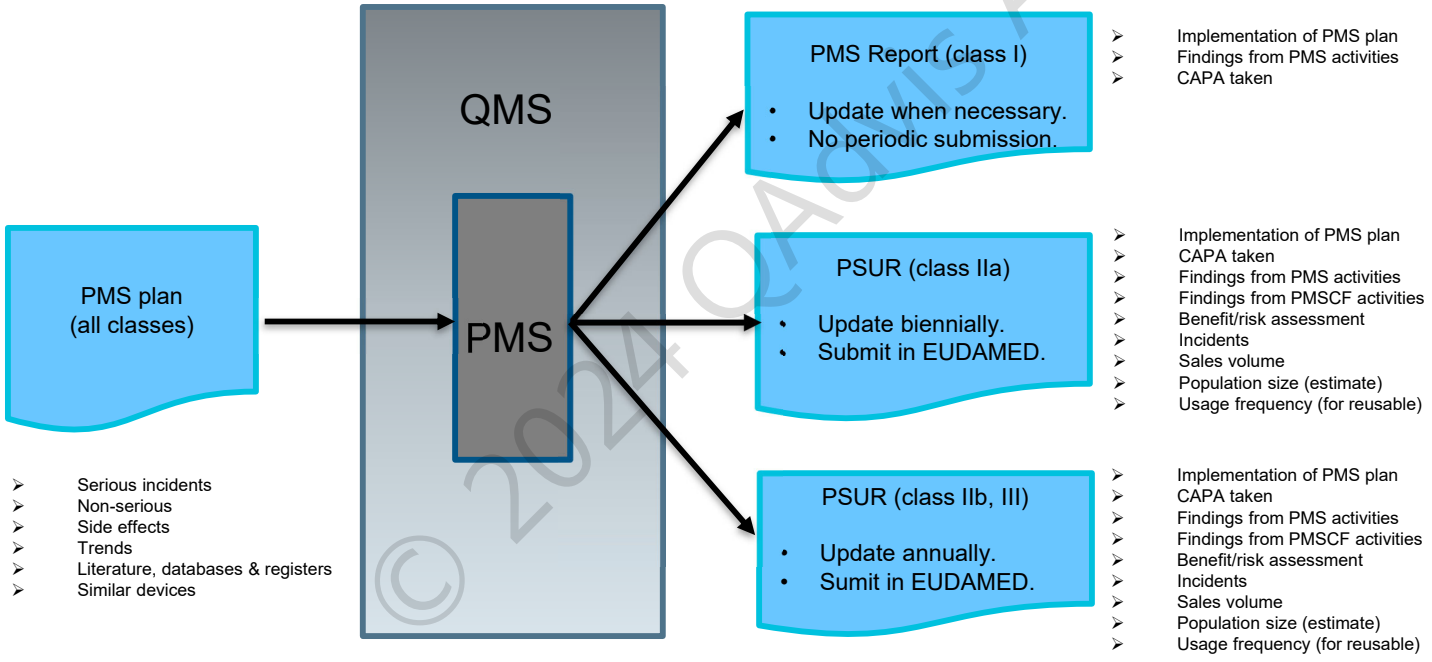
Reactive:

- Data from vigilance activities (serious incidents, FSCAs, trend reporting)



PMCF*, Post-market Clinical Follow-up

Post-market surveillance (MDR)



VIGILANCE ; DEFINITIONS & CRITERIA

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Definitions from art.2

- ‘recall’, (art 2(62))
  - » any measure aimed at achieving the return of a device that has already been made available to the end user
- ‘withdrawal’, (art 2(63))
  - » any measure aimed at preventing a device in the supply chain from being further made available on the market

Definitions from art 2, continued

- ‘field safety corrective action’, FSCA (art 2 (68))
  - a corrective action taken by a manufacturer for technical or medical reasons to prevent or reduce the risk of a **serious incident** for devices made available on the market
- ‘field safety notice’, FSN (art 2(69))
  - a communication sent by a manufacturer to users or customers

Definitions from art 2, continued

- ‘incident’ (art 2 (64))
  - » any malfunction or deterioration in the characteristics or performance
  - » including use-error due to ergonomic features
  - » inadequacy in the information supplied by the manufacturer
  - » undesirable side-effect

- ‘serious incident’ (art 2 (65))
  - » any incident that directly or indirectly led, might have led / might lead to any of (a)-(c)

  (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

Criteria for reporting a “serious incident”

Any incident which meets all three basic reporting criteria A – C listed below is considered a serious incident and must be reported to the relevant competent authority:

A. an incident (Article 2(64) MDR) has occurred, and

*B. the **incident directly** or **indirectly led**, **might have led** or **might lead** to any of the outcomes of a serious incident (Article 2(65) MDR), and*

C. a causal relationship between the serious incident and the manufacturer's device has been established, is reasonably possible or suspected.

Following devices are required to be reported

- All ***CE-marked medical devices***, ***IVD devices***, and active implantable medical devices
- ***Custom-made medical devices***
- ***National Medical Information Systems (NMI)***

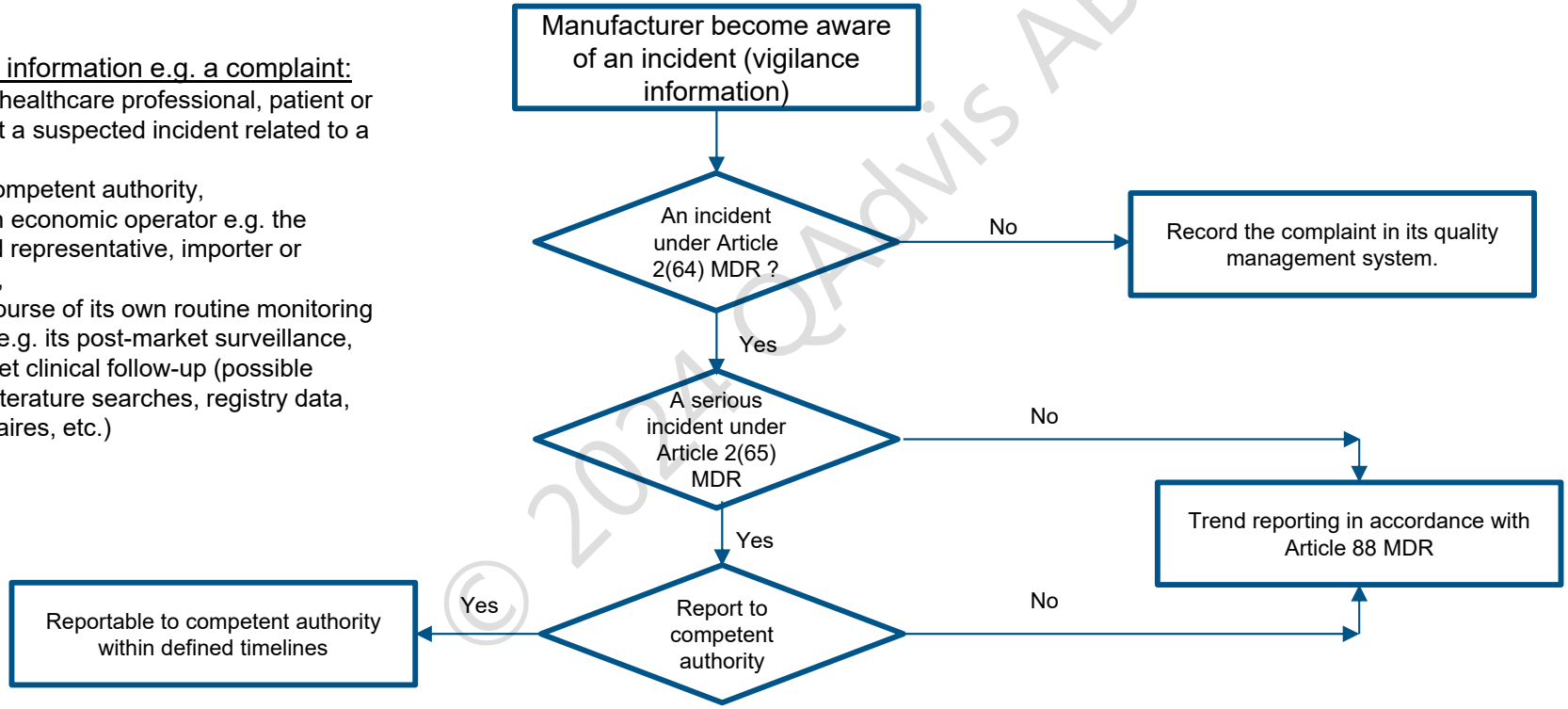
Serious Adverse Events (SAE) *should be reported within clinical investigations or performance studies for:*

- Medical devices without CE marking under clinical investigation
- IVD devices under performance evaluation

Process for management of incidents and serious incidents

Vigilance information e.g. a complaint:

- From a healthcare professional, patient or user about a suspected incident related to a device,
- via a competent authority,
- from an economic operator e.g. the authorised representative, importer or distributor,
- in the course of its own routine monitoring activities, e.g. its post-market surveillance, post-market clinical follow-up (possible sources: literature searches, registry data, questionnaires, etc.)



The timelines outlined in Article 87(3) to (5) MDR

A serious public health threat:

must be reported immediately after the manufacturer becomes aware of the threat and

no later than **2 days** (calendar days)

Death or an unanticipated serious deterioration in a person's state of health

must be reported immediately after established/suspected causal relationship between the device and serious incident and

no later than **10 days** (calendar days)

Any serious incident:

must be reported immediately after causal relationship is established/causal relationship is reasonably possible between the device and serious incident and

no later than **15 days** (calendar days)

MANUFACTURER INCIDENT REPORT, MIR

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EUROPEAN COMMISSION

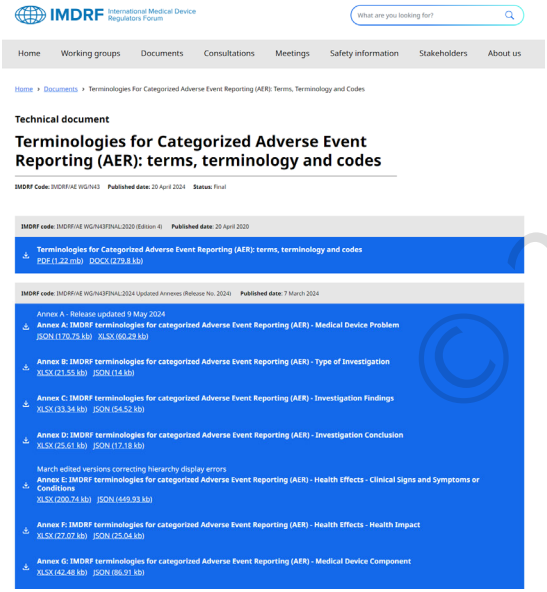
European Commission > DocsRoom > Document detail

Manufacturer incident report 2020

Document date: 11/06/2020 - Created by GROW.R.2.DIR - Publication date: n/a - Last update: 12/06/2020

Download links:

Manufacturer incident report 2020 - please save this file and open it with Adobe Acrobat (188 KB)



Manufacturer Incident Report (MIR) for Serious Incidents (MDR/IVDR) and Incidents (AIMDD/MDD/IVDD)

Reporting Template Version 7.2.1
European Union Medical Devices Vigilance System

Import XML | Align form after import

Section 1: Administrative information

1.1 Corresponding competent authority

a. Name of receiving national competent authority (NCA)

b. EUDAMED number of NCA

c. Reference number assigned by NCA for this incident

d. Reference number assigned by EUDAMED for this incident

1.2 Date, type, and classification of incident report

a. Date of submission (e.g. 2012-10-23)

b. Date of incident (e.g. 2012-10-23) to

c. Manufacturer awareness date (e.g. 2012-10-23)

d. Type of report
- Initial
- Follow up
- Combined initial and final
- Final (Reportable incident)
- Final (Non-reportable incident)

e. In case of initial and follow-up reports, please indicate the expected date of the next report (e.g. 2012-10-23)

f. Classification of incident
- Serious public health threat
- Death
- Unanticipated serious deterioration in state of health
- All other reportable incidents

1.3 Submitter information

1.3.1 Submitter of the report

a. Manufacturer | Authorised representative | Other, please specify

b. Manufacturer's reference number for this incident

Overview of the Form and MIR Form

Section 1: Administrative Information

- **Dates for submission**, incident occurrence and Manufacturer awareness date.
- **Type of report**: Initial, Follow-up, Combined Initial and Final, Final, **Final(Non-reportable incident).**
- **Classification of the incident:** *Serious threat to public health*, *Unexpected serious deterioration in health condition*, *Other reportable incidents.*
- **Date of the next report**

Section 2: Information about the Medical Device (MD)

- UDI product identification and other unique IDs.
- Medical device name and description.
- Lot/batch number(s), Software version, Date when device was implanted, Date when device was explanted and more.
- Risk class and countries where the product was distributed.

Section 3: Incident Description/Nature of Incident

- Description of the incident and patient's health condition.
- MD problem coding (IMDRF Medical Device Problem Codes).
- Number of affected patients and patient information.

Investigation and Results

Section 4: Manufacturer Analysis

- Description of the root cause or most probable root cause.
- Investigation methods, including interviews and testing of replacement products.
- Explanation and justification of the investigation's conclusions.

4.2 Specific Parts of the Investigation

- Evidence of a causal relationship between the medical device and the problem.
- Review and evaluation of the risk assessment post-incident.
- Relevant coding for root cause investigation (IMDRF Annex B, C, D, G).
- Immediate actions and corrective/preventive measures taken.

4.3 Similar Incidents

- Cumulative numbers based on the number of sold/installed products, tests performed, etc.

International Medical Device Regulators Forum (IMDRF)

The terminologies in this document are for:

1. Reporters of adverse events required to report to authorities per relevant regulations.

1. Regulatory authorities (NCAs or supranational bodies) collecting and analyzing this data to protect patient and public health.

- Annex A: Medical Device Problem
- Annex B: Cause Investigation - Type of Investigation
- Annex C: Cause Investigation - Investigation Findings
- Annex D: Cause Investigation – Investigation Conclusion
- Annex E: Health Effects - Clinical Signs and Symptoms or Conditions
- Annex F: Health Effects - Health Impact
- Annex G: Medical Device Component

+ A01 - Patient Device Interaction Problem
Problem related to the interaction between the patient and the device.

+ A02 - Manufacturing, Packaging or Shipping Problem
Problem associated with any deviations from the documented specifications of the device that relate to nonconformity during manufacture to the design of an item or to specified manufacturing, packaging or shipping processes (out of box problem).

+ A03 - Chemical Problem
Problem associated with any from the documented specifications of the device that relate to any chemical characterization, i.e., element, compound, or mixture.

- A04 - Material Integrity Problem
Problem associated with any deviations from the documented specifications of the device that relate to the limited durability of all material used to construct device.

+ A0401 - Break
Problem associated with undesired damage or breakage of those materials used in the device construction.

A0402 - Burst Container or Vessel
Problem associated with the pressure inside a vessel or container rising to such a degree that the container ruptures.

A0403 - Explosion
Problem associated with the violent bursting due to the sudden expansion of air, gas or fluid.

ASSESSMENTS AND EXAMPLES

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Reports from Healthcare Providers or Intended Users

Reports from healthcare providers or intended users must be taken seriously, thoroughly investigated, and the outcomes of these investigations can significantly impact the product. Such reports can lead to:

- Product Modifications/Design Improvements
- Changes in Production/Manufacturing Processes
- Enhanced User Instructions and Clearer Product Labeling
- Global or European Product Recalls when the manufacturer's investigation identifies significant safety risks.

An example deviation management stepwise

Collapsible Shower Chair Incident; A nursing home reports that a shower chair collapsed while in use. The incident ***led to the user being hospitalized***. In this case, the following steps should be taken:

1. Contact the nursing home to gather detailed information about the incident.
2. Conduct a thorough incident analysis and examine the product involved.
3. Inspect the chair for any damage, weaknesses, and proper labeling.
4. Investigate the product's manufacturing history and review risk management procedures to determine if the identified risk was previously addressed.
5. Identify the root cause or potential root cause of the failure.
6. Develop and implement preventive measures to avoid recurrence.

5 common misconceptions/mistakes in PMS

- only involves documenting customer complaints
- Incomplete documentation and traceability
- Incorrect risk assessment and safety considerations
- Neglecting current product issues; prioritizing new designs
- Poor communication with regulatory authorities and users

FSCA and FSN

Field safety corrective action (FSCA)

A FSA under MDR aims to prevent or reduce serious risks associated with medical devices, involving measures like **device return**, **modifications**, **advice on usage**, **software changes**, **exchanges**, **destruction**, or **safety inspections**.

FSCA must be **implemented in all countries** where the affected medical device is on the market or in use, and/or where diagnostic result services were provided.

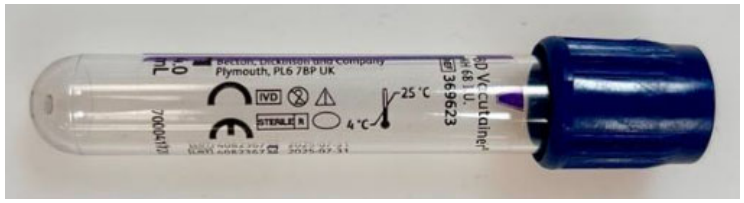
Notify customers of FSCA via a **Filed Safety Notices** (FSN).

Recall due to mistake in production line

Recall

due to poor information for safety

due to mislabeling



Recall

svt NYHETER Nyheter Lokalt Sport SVT Play Barr

/ NORRBOTTEN

Sår och stora blåsor på fötterna har blivit ett problem för försvaret i Arvidsjaur och Halmstad. Rekryter har halkat efter i utbildningen på grund av smärtor. Foto: TT

Skavsårstejp ställer till problem för försvaret – sår och stora blåsor på soldaternas fötter

UPPDATERAD 14 SEPTEMBER 2021 PUBLICERAD 13 SEPTEMBER 2021

Sår och utslag på fötterna för värnpliktiga och personal inom försvaret i Arvidsjaur och Halmstad har fått värnpliktiga att halka efter i utbildningen. Men såren kommer inte av långa strapatser i trånga skor – istället handlar det om en skavsårstejp som ska hjälpa vid just skavsår.

Enligt en anmälan som försvarshälsan vid Jägarbataljonen i Arvidsjaur gjort till Läkemedelsverket har problemen med såren, som pågått i ett år, gjort att flera värnpliktiga och anställda tvingats ställa in fysiska aktiviteter och därför kommit efter i vissa utbildningsmoment.

I anmälan skriver försvarshälsans läkare att det handlar om "stora blåsor där huden sedan faller av." och att "cirka tio personer har bara sedan i juni fått en varning tillagd i journalen pga stora besvär av produkten"

Såren ska för de flesta inte heller läkt helt efter två veckor utan skavsårstejpen.

Problem även i Halmstad

Även försvarshälsan vid Luftvärnsregemente Lv 6 i Halmstad har anmält problem med tejpen till Läkemedelsverket. Där har cirka 30 rekryter fått blåsor och sår efter att ha använt produkten.

Både i Halmstad och Arvidsjaur har nu användandet av produkten stoppats, att det inte gjorts tidigare är för att produkten förut använts med goda resultat vilket gör att försvarshälsan i Arvidsjaur misstänker att något förändrats i tillverkningen.

Försvarshälsan i Halmstad har även kontaktat tillverkaren som stoppat produktionen för att utreda det hela vidare.

svt NYHETER Nyheter Lokalt Sport SVT Play Barr

/ NORRBOTTEN

En skavsårstejp som under ett år vållat stora problem för Försvarsmakten stoppas nu. Foto: Mikael Fritzon/TT

Nu förbjuder Försvarsmakten skavsårstejp – värnpliktiga har tagits ur tjänst

UPPDATERAD 26 SEPTEMBER 2022 PUBLICERAD 26 SEPTEMBER 2022

En skavsårstejp som i ett år vållat stora problem för Försvarsmakten på flera håll i landet förbjuds. Detta efter nya anmälningar till Läkemedelsverket där bland annat värnpliktiga i Halmstad tagits ur tjänst eftersom de inte kunnat gå ordentligt eller ha på sig skor på grund av blåsor och sår.

SVT Nyheter Norrbotten har flera gånger rapporterat om att en skavsårstejp, som används för att motverka skavsår, vållat problem för Försvarsmakten i orter som Arvidsjaur, Luleå och Halmstad.

Bland annat har värnpliktiga i Arvidsjaur fått sår och utslag på fötterna som gjort att de riskerat att halka efter i utbildningen.

Nu har flera nya anmälningar om skavsårstejpen kommit in till Läkemedelsverket.

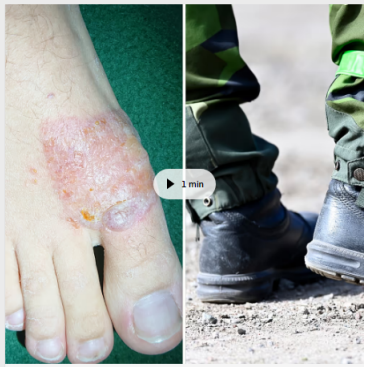
Värnpliktiga har tagits ur tjänst

Till exempel har värnpliktiga i Halmstad tagits ur tjänst eftersom de inte kunnat gå ordentligt på grund av blåsor, sår, svullnad och klåda.

Markus Karumo som är Försvarsmaktens chefsläkare säger att ett användarförbud av skavsårstejpen infördes från och med den 2 september.

svt NYHETER Nyheter Lokalt Sport SVT Play Bar

/ SKÅNE



Flera rekryter fick allvarliga problem efter att ha använt tejp mot skoskav under marscher. Se hur fötterna såg ut i videon. Foto: Privat/TT

Värnpliktiga kan få livslång allergi av tejp mot skoskav

UPPDATERAD 10 MARS 2024 PUBLICERAD 8 MARS 2024

Tejp som använts för att förebygga skavsår har vid flera tillfällen orsakat besvär inom försvaret. Problemen riskerar att bli långvariga. Undersökningar har visat att rekryter i Halland och Skåne blivit allergiska – för resten av livet.

SVT har tidigare rapporterat om fall i Arvidsjaur, Luleå och Halmstad där värnpliktiga och personal inom försvaret fått hudbesvär efter att ha tejpat fötterna inför marscher.

Blivit allergiska

En studie som gjorts på Skånes universitetssjukhus, Sus, visar hur majoriteten av en grupp rekryter, som deltog i en övning i Halland under sommaren 2021, utvecklat kontaktallergier efter att ha tejpat fötterna under en längre period. Ämnet man reagerat på heter kolofonium, en typ av harts som används som klister i den medicintekniska tejpen.

2022 införde Försvaret ett användarförbud av tejpen Optiplaste C och tillverkaren valde samma år att återkalla den.

5 Key Advices

- **Follow-up your actions on the market**
- **Retrieve relevant data, examine the product**
- **Determine Root Causes Analysis for the event**
- **Training of economic operators**
- **Read relevant guidance like MDCG 2023-3.**

*PMS activities are labor-intensive; ensure you have the **necessary resources**, which can be outsourced.*

Finally

"Love our deviations!"

– *Leif Östling (CEO of Scania)*

Useful links

Rapportering av allvarliga tillbud | Läkemedelsverket (lakemedelsverket.se)

Rapportering av korrigerande säkerhetsåtgärder och säkerhetsmeddelande | Läkemedelsverket (lakemedelsverket.se)

Adverse Event Terminology | International Medical Device Regulators Forum (imdrf.org)

Guidance - MDCG endorsed documents and other guidance - European Commission (europa.eu)

Additional Guidance Regarding the Vigilance System as outlined in MEDDEV 2.12-1 rev. 8

Devices Vigilance System – MEDDEV 2.12/1 rev. 8

Q&A

QAdvis support you with:

- PMS procedures.
- PMCF/PMPFP plans and reports.
- Collecting data/Literature review.
- Surveillance and assessment of upcoming changes in relevant standards and regulations.
- Provide training (customized or in open class).
- Complaint and Vigilance handling (including FSCA/FSN).

Our other services within quality, regulatory and clinical evidence