swissmedic

Online event

Information on the new medical devices regulation

Thursday, 2 September 2021

Post-market surveillance, vigilance and market surveillance

Economic operators, hospitals and professionals

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Agenda

1. Introduction
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    2. Why is reporting necessary?
    3. What is a serious / reportable incident?
2. Tasks for manufacturers, authorised representatives, importers, distributors
    1. Serious incidents
    2. FSCA
    3. PSR
    4. Trend Reports
    5. PSUR / PMS Report
3. Tasks for hospitals / professionals
    1. Serious incidents
    2. FSCA
4. Materiovigilance at Swissmedic

Scope

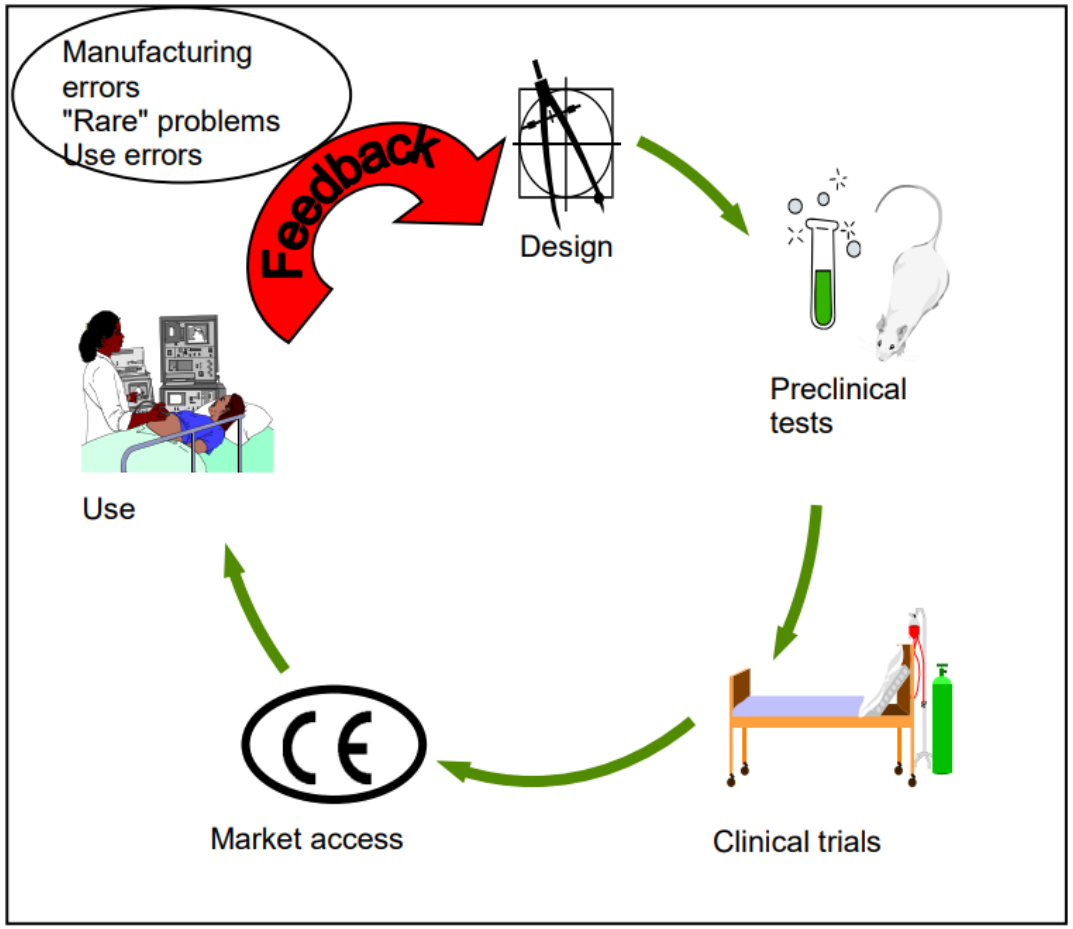
- The presentation addresses the reporting obligations based on MedDO / MDR
- It therefore covers all devices specified in MDD and AIMD ("Legacy Devices") and MDR, but not IVDD or IVDR devices

Why is reporting necessary?

Manufacturers can improve their devices only if they are **aware** of the weaknesses and risks of their devices on the market.

Aim of reporting:

To avoid recurrences of incidents attributable to problems that can be traced to the design, manufacture or use of medical devices.



Definition according to MedDO of 1 July 2020 (version: 26.05.2021) and MDR (Regulation (EU) 2017/745)

Incident:

- Malfunction or deterioration in the characteristics or performance of a device made available on the market
- including use-error due to ergonomic features
- Inadequacy in the information supplied by the manufacturer
- Undesirable side effect

Art. 4 para. 2 MedDO in conjunction with Art. 2 point 64 MDR

Serious incident:

Incident that led or might have led to any of the following:

- Death
- Temporary or permanent serious deterioration in a person's state of health
- Serious public health threat

Art. 4 para. 2 MedDO in conjunction with Art. 2 point 65 MDR

Definition according to MedDO / MDR

The following must be reported:

Any serious incident […] **except** **expected side effects** which are clearly documented in the product information, quantified in the technical documentation and are subject to trend reporting pursuant to Article 88;

Art. 66 Abs. 1 let. a MedDO, exemptions in Art. 66 para. 2 MedDO in conjunction with Art. 87 para. 1a MDR

What is a side effect?

Art. 4 para. 2 MedDO in conjunction with Art. 2 point 64 MDR:

*"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 **or***

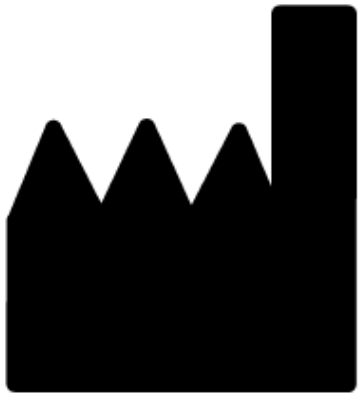
*any undesirable **side effect**;*

→ Side effects are **not** associated with a malfunction of the device, but rather with an **adverse reaction of the patient** to a properly working device

Definition according to MedDO and MDR

Exemptions, additional information, interpretation – MEDDEV Guidelines are no longer valid under MedDO in conjunction with MDR

2. Tasks of economic operators: Manufacturers, authorised representatives, importers, distributors



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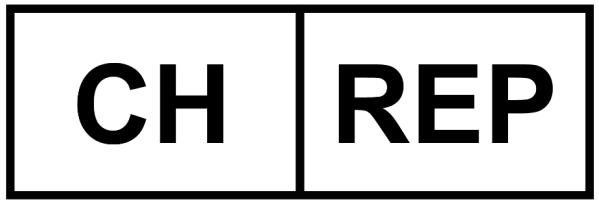

2)

3)

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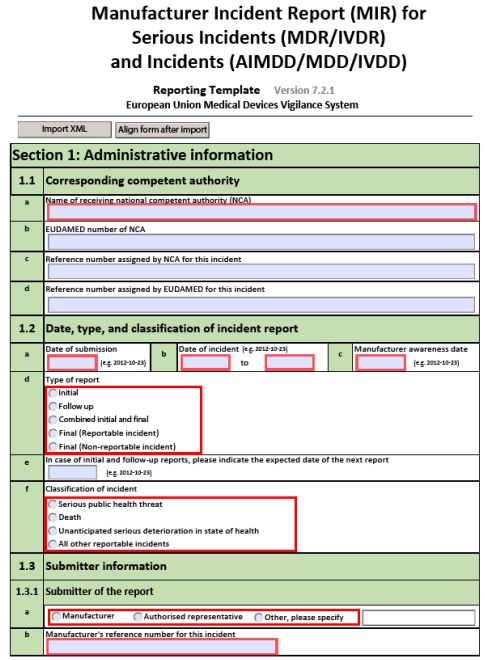
2) https://www.swissmedic.ch/dam/swissmedic/de/dokumente/medizinprodukte/mep_urr/symbol_ch-rep.png.download.png/MEP-Symbol_CH-REP.png
3) https://www.iso.org/obp/ui#iso:grs:7000:3725
4) https://www.iso.org/obp/ui#iso:grs:7000:3724

Reporting serious incidents

Manufacturers must report to SMC any serious incident occurring in Switzerland, Art. 57 para. 2 and Art. 66 para. 1 let. a MedDO in conjunction with Art. 87 para. 1a MDR

→ by e-mail using the MIR form (Art. 66 para. 5 MedDO)



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

Important:

Swiss authorised representatives:

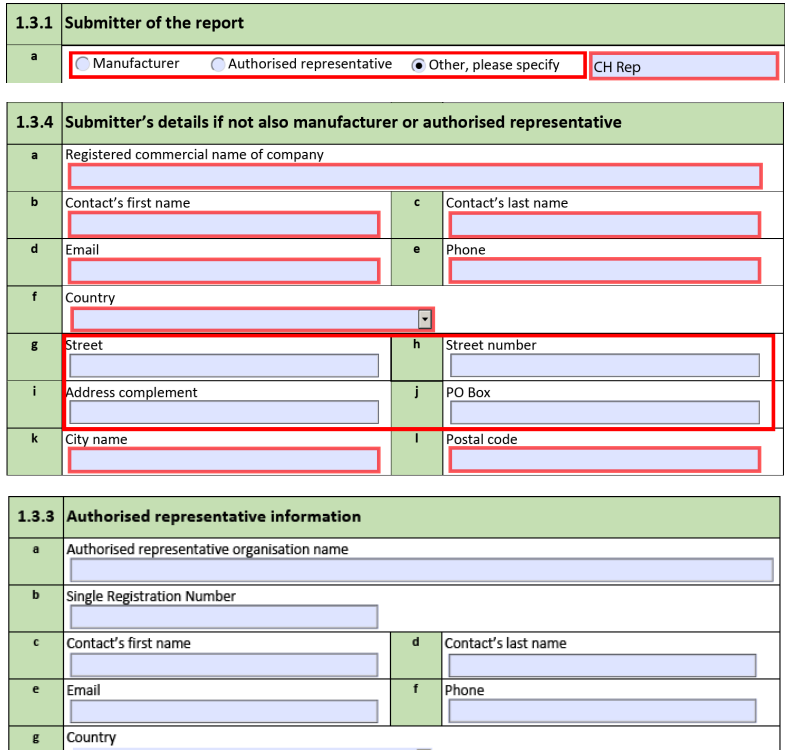
- These reports can also be submitted by the Swiss authorised representative if the latter has access to the information contained in the form (e.g. from the technical documentation).
- The representative is responsible for reporting serious incidents (Art. 66 para. 2bis MedDO)

Reporting serious incidents

Information on the content of the MIR form

- If you, as a **Swiss authorised representative** or **manufacturer domiciled outside Switzerland**, report serious incidents, you must select the "Other, please specify" option in section 1.3.1 of the MIR form "Submitter of the report" and enter "CH Rep" in the adjacent text field.
- The contact details of the Swiss authorised representative should be entered in section 1.3.4 "Submitter's details".
- Please also state the **EU authorised representative** (for manufacturers domiciled outside Switzerland and the EU)

- When serious incidents are reported, Swissmedic will also check whether the manufacturer or authorised representative is registered according to Art. 55 and 104b MedDO (**CHRN**) (spot checks)



1.3.1	Submitter of the report	
a	○ Manufacturer ○ Authorised representative ◉ Other, please specify	CH Rep

1.3.4	Submitter's details if not also manufacturer or authorised representative		
a	Registered commercial name of company		
b	Contact's first name	c	Contact's last name
d	Email	e	Phone
f	Country		
g	Street	h	Street number
i	Address complement	j	PO Box
k	City name	l	Postal code

1.3.3	Authorised representative information		
a	Authorised representative organisation name		
b	Single Registration Number		
c	Contact's first name	d	Contact's last name
e	Email	f	Phone
g	Country		

Reporting serious incidents

Information on the content of the MIR form

- For all devices requiring a UDI (MDR devices, excluding custom-made devices): entering UDI details

Section 2: Medical device information					
2.1	**Unique Device Identification (UDI)**				
a	UDI device identifier/Eudamed ID	Unknown	**b**	UDI production identifier	Unknown
c	Basic UDI-DI/Eudamed-DI	Unknown	**d**	Unit of use UDI-DI	

Reporting serious incidents: Obligations of importers and distributors

Importers / Distributors

- are responsible for the immediate forwarding of reports to the manufacturer
- Keeping a register / Collecting reports

Art. 53 para. 4 MedDO in conjunction with Art. 13 para. 6 and 8 MDR; Art. 54 para. 4 MedDO in conjunction with Art. 14, para. 5 MDR

Timelines according to MedDO in conjunction with MDR

The following basically applies: Report as soon as the manufacturer becomes aware of them (Art. 66, para. 1 let. a MedDO)

Specified maximum timelines: 15, 10, 2 days (Art. 66 para. 2 MedDO. in conjunction with Art. 87 paras. 2–5 MDR)

→2: If the serious incident evidently constitutes, or has the potential to constitute, a serious and imminent threat to the life or health of a large number of persons (**serious public health threat**)

→10: in case of **death** or **unanticipated** serious deterioration in a person's state of health

→15: all other cases

	MO	DI	MI	DO	FR	SA	SO
4	25	26	27	28	29	30	31
5	1	2	3	4	5	6	7
6	8	9	10	11	12	13	14
7	15	16	17	18	19	20	21
8	22	23	24	25	26	27	28
9	1	2	3	4	5	6	7

Serious incidents: Process requirements

Principle:

- Immediate investigation of the incident and risk assessment by the manufacturer

Device investigation:

- Manufacturer may not perform any destructive investigations on the device before informing the competent authority.
- Proposal currently being prepared in the MDCG (Guideline is not yet published):
  - Written information sent to the authority in connection with the incident report, stating that destructive investigation will start after 10 days if the authority has not replied by then.

  → However, Swissmedic does not issue any official "release"

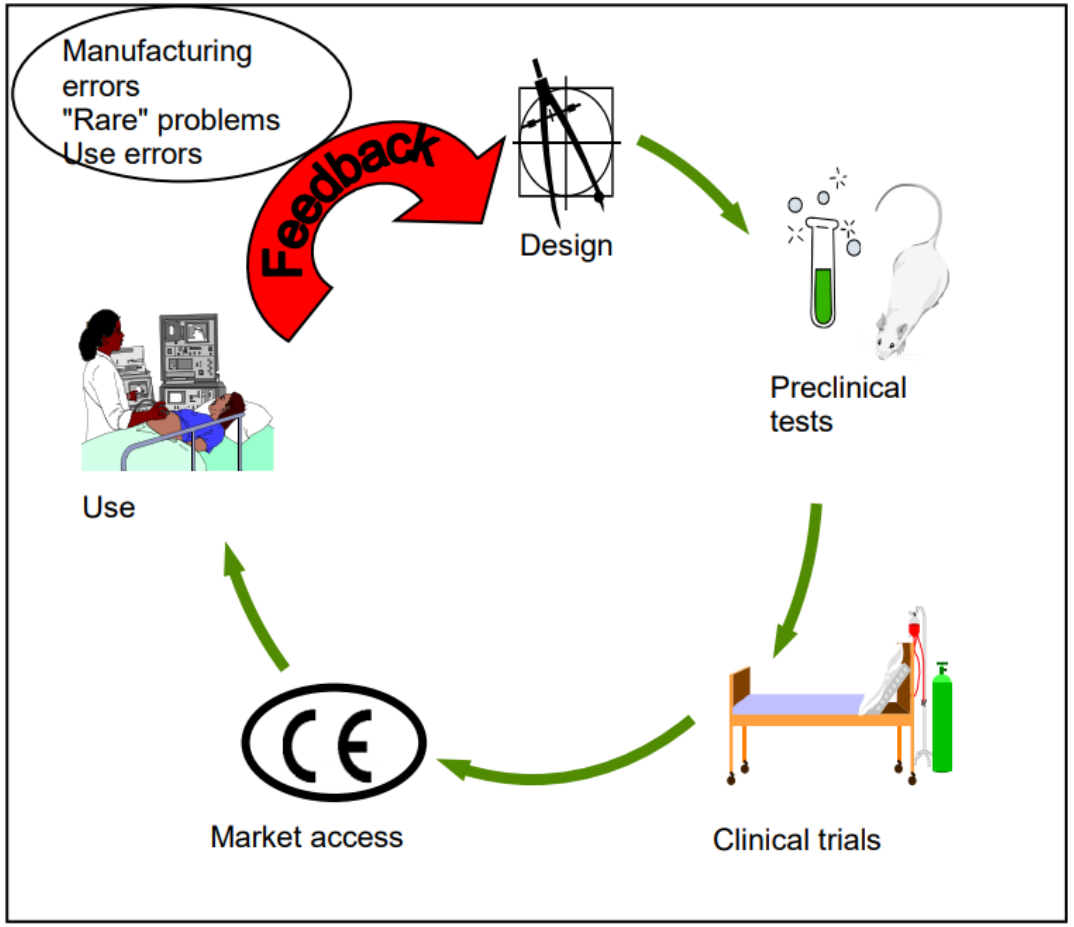
  (Art. 66 para. 2 MedDO in conjunction with Art. 89 para. 1 MDR)

Field Safety Corrective Actions

FSCA: Action taken to reduce the risk of a direct or indirect threat and/or impairment of health.

Examples:

- Physical recall
- A replacement
- A modification of a device or its instructions for use
- SW update
- Information provided to users to reduce the risk of a possible health threat



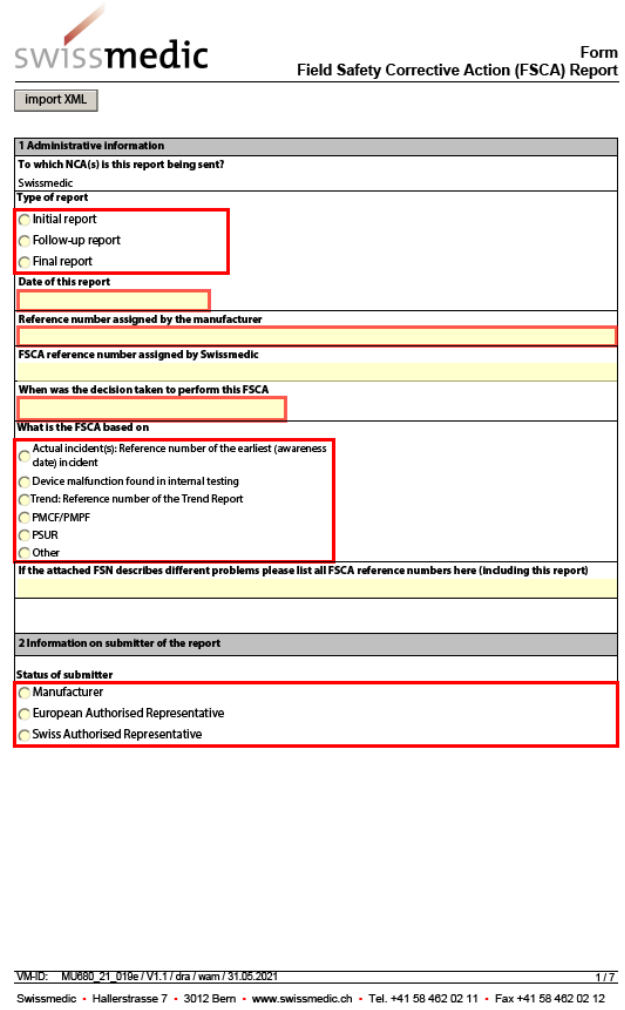
FSCA reporting obligations

- Reporting by the **manufacturer** (Art. 57 para. 2 and Art. 66 para. 1 let. b MedDO in conjunction with Art. 87 para. 1 let. b MDR)
- by e-mail (specific CH-FSCA form, FSN, further information) (Art. 66 para. 2 and 5 MedDO in conjunction with Art. 87 para. 1 and Art. 89 para. 8 MDR)

Important:

Swiss authorised representatives:

- These reports can also be submitted by the Swiss authorised representative if the latter has access to the information contained in the form (e.g. from the technical documentation).
- The representative is responsible for reporting the FSCA (Art. 66 para. 2bis MedDO)



swissmedic

Form
Field Safety Corrective Action (FSCA) Report

import XML

1 Administrative information

To which NCA(s) is this report being sent?
Swissmedic

Type of report
- Initial report
- Follow-up report
- Final report

Date of this report

Reference number assigned by the manufacturer

FSCA reference number assigned by Swissmedic

When was the decision taken to perform this FSCA

What is the FSCA based on
- Actual incident(s): Reference number of the earliest (awareness date) incident
- Device malfunction found in internal testing
- Trend: Reference number of the Trend Report
- PMCF/PMPF
- PSUR
- Other

If the attached FSN describes different problems please list all FSCA reference numbers here (including this report)

2 Information on submitter of the report

Status of submitter
- Manufacturer
- European Authorised Representative
- Swiss Authorised Representative

VM-ID: MU680_21_019e / V1.1 / dra / wam / 31.05.2021 1 / 7

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FSCAs: Obligations of manufacturers according to MedDO in conjunction with MDR

- **Manufacturer** ensures that the FSN reaches the **user**
- Evaluation of the FSN by the competent **authority** before it is sent to customers (except in urgent cases)

(Art. 66 para. 2 MedDO in conjunction with Art. 89 para. 8 MDR)

Art. 2 point 37 MDR (Art. 4 para. 2 MedDO) defines a **user** as: Any healthcare professional or lay person who uses a device.

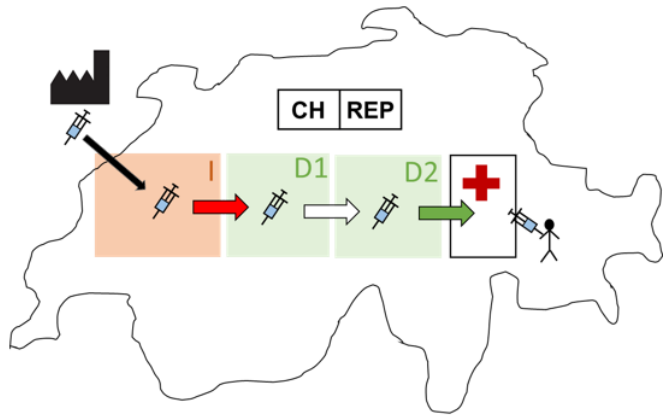
Art. 25 MDR – the economic operators must be able to **identify**:

Art. 47c para. 1 TPA – the economic operators must **disclose**:

a) b) Any economic operator to whom they have directly **supplied** a medical device

b) a) Any economic operator who has directly **supplied** them with a device

c) c) Any **healthcare institution or healthcare professional** to which they have directly supplied a device.



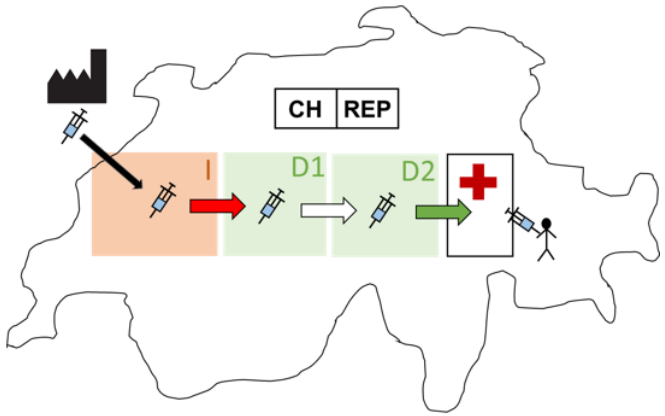
FSCAs: Obligations of distributors and importers

- Importers and distributors may not place devices on the market unless they conform with the requirements
- Cooperation with manufacturers / authorised representatives and authorities in order to restore conformity or recall a device
- Cooperation with manufacturers / authorised representatives for traceability
- Duty of disclosure for 10 or 15 years (implants)

→hence the **cooperation in implementing FSCAs**, e.g.

- Quarantine / no onward sale of devices that are not located at the importer/ distributor
- Procedure for recalls at the end customer
- Forwarding of information
- Implementation of measures on devices that are already on the market

Art. 53 para. 3 and 4 MedDO; Art. 54 para. 3 and 4 MedDO, Art. 64 para. 1 and 2 MedDO // Art. 47c TPA in conjunction with Art. 13 para. 1, 2 and 7 MDR; Art. 14 para. 1, 2 and 4 MDR and Art. 25 MDR



Periodic Summary Report

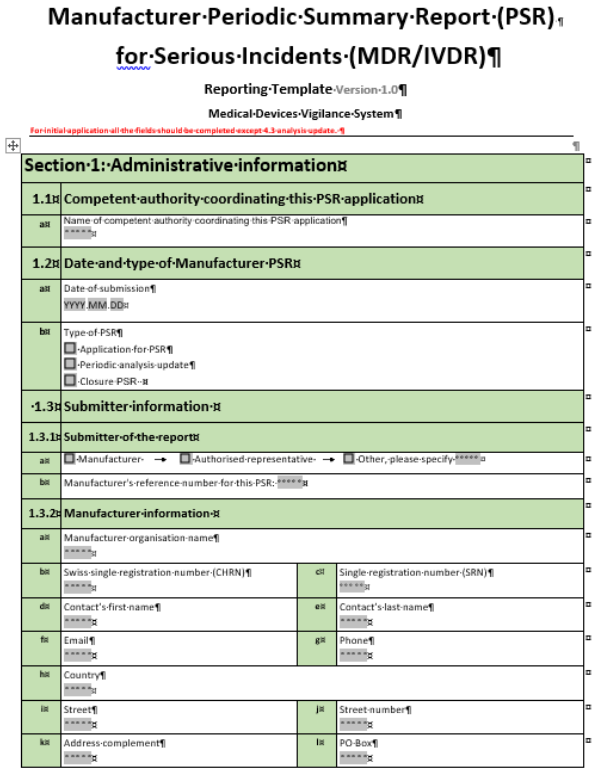
Art. 66 para. 1 and 2 MedDO, Art. 87 para. 9 MDR

Conditions:

- Similar incidents with known cause
- Covered by FSCA
- Incidents are common and well documented

Reporting process:

- Reporting by the **manufacturer** or the **CH authorised representative**
- by e-mail, form + Excel
- The form, content and frequency must be discussed with Swissmedic.
- Important: If foreign manufacturers are involved, the CH authorised representative is responsible for reporting serious incidents (Art. 66 para. 2bis MedDO)



Manufacturer Periodic Summary Report (PSR)
for Serious Incidents (MDR/IVDR)
Reporting Template Version 1.0
Medical Devices Vigilance System

For initial application all the fields should be completed except 4.3 analysis update.

Section 1: Administrative information			
1.1	**Competent authority coordinating this PSR application**		
a	Name of competent authority coordinating this PSR application *****		
1.2	**Date and type of Manufacturer PSR**		
a	Date of submission YYYY MM DD		
b	Type of PSR ☐ Application for PSR ☐ Periodic analysis update ☐ Closure PSR		
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 PSR: *****		
1.3.2	**Manufacturer information**		
a	Manufacturer organisation name *****		
b	Swiss single registration number (CHRN) *****	ci	Single registration number (SRN) *****
di	Contact's first name *****	e	Contact's last name *****
f	Email *****	g	Phone *****
h	Country *****		
i	Street *****	j	Street number *****
k	Address complement *****	l	PO Box *****

Trend reporting

1)

Reporting in case of:

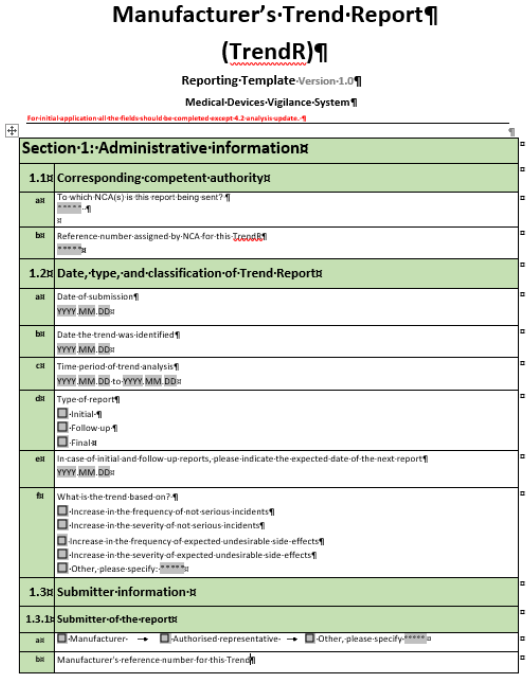
- statistically significant increase in the frequency or severity
  (Art. 66 para. 2 MedDO in conjunction with Art. 88 para. 1 MDR)

The subject of trend reports are:

- Non-serious incidents and expected undesirable side effects with a significant impact on the benefit-risk analysis (Art. 66 para. 2 MedDO in conjunction with Art. 88 MDR)

The **manufacturer or Swiss authorised representative** submits reports using a form / e-mail (Art. 66 para. 2 and 2bis MedDO in conjunction with Art. 88 MDR)

The manufacturer must specify a trend definition in the Post-market Surveillance Plan: Methodology for determining statistically significant increases in frequency or severity. (Art. 66 para. 2 MedDO in conjunction with Art. 88 para. 1 MDR)



Manufacturer's Trend Report

(TrendR)

Reporting Template Version 1.0

Medical Devices Vigilance System

For initial application all the fields should be completed except 4.2 analysis update.

Section 1: Administrative information	
1.1	**Corresponding competent authority**
a1	To which NCA(s) is this report being sent? *****
b1	Reference number assigned by NCA for this TrendR *****
1.2	**Date, type, and classification of Trend Report**
a1	Date of submission YYYY MM DD
b1	Date the trend was identified YYYY MM DD
c1	Time period of trend analysis YYYY MM DD to YYYY MM DD
d1	Type of report ☐ Initial ☐ Follow up ☐ Final
e1	In case of initial and follow up reports, please indicate the expected date of the next report YYYY MM DD
f1	What is the trend based on? ☐ Increase in the frequency of not serious incidents ☐ Increase in the severity of not serious incidents ☐ Increase in the frequency of expected undesirable side effects ☐ Increase in the severity of expected undesirable side effects ☐ Other, please specify *****
1.3	**Submitter information**
1.3.1	**Submitter of the report**
a1	☐ Manufacturer → ☐ Authorised representative → ☐ Other, please specify *****
b1	Manufacturer's reference number for this Trend

1) graph-line-trend-analytics-magnifying-glass-ss-1920.jpg (1920×1080) (bluebridge-vres.eu)

Periodic Safety Update Report und Post-Market Surveillance Report

Plan and report on post-market surveillance (PMS report)

Art. 58 and 59 MedDO in conjunction with Art. 84 and 85 MDR

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

Plan and safety report (Periodic Safety Update Report, PSUR)

Arts. 58 and 60–62 MedDO in conjunction with Art. 84 and 86 MDR

- Class IIa: Update when necessary, but at least every two years
- Class IIb and class III (incl. implantable devices): updated at least annually

→ The manufacturers submit the safety report to the Designated Bodies

- Class III and implantable devices
  - Review by Designated Body, which determines the outcome of its review with details of any action taken

Safety report and outcome of the review with action (if present):

→ Submitted to Swissmedic on request by **manufacturers or their authorised representatives**

Obligations of economic operators according to MedDO

Art. 78 of the Medical Devices Ordinance (MedDO): **Duty to cooperate and provide information**

Economic operators that place a device **on the market** in Switzerland or in a contracting state, and economic operators, professionals and healthcare institutions that **make a device available on the market** or **put it into service** in Switzerland or a contracting state have a duty to cooperate on matters of enforcement. In particular, they must provide, free of charge, all necessary information and all necessary proof and documentation to the enforcement bodies.

Take-home messages

- **Manufacturers** or **Swiss authorised representatives** are responsible for compliance with the reporting obligations
- **Importers and distributors** cooperate in collecting serious incidents and support the manufacturer in tracing its devices and implementing FSCAs
- Swissmedic supplies the **forms** for reporting serious incidents, FSCAs, PSRs and trends

3. Tasks for hospitals and professionals

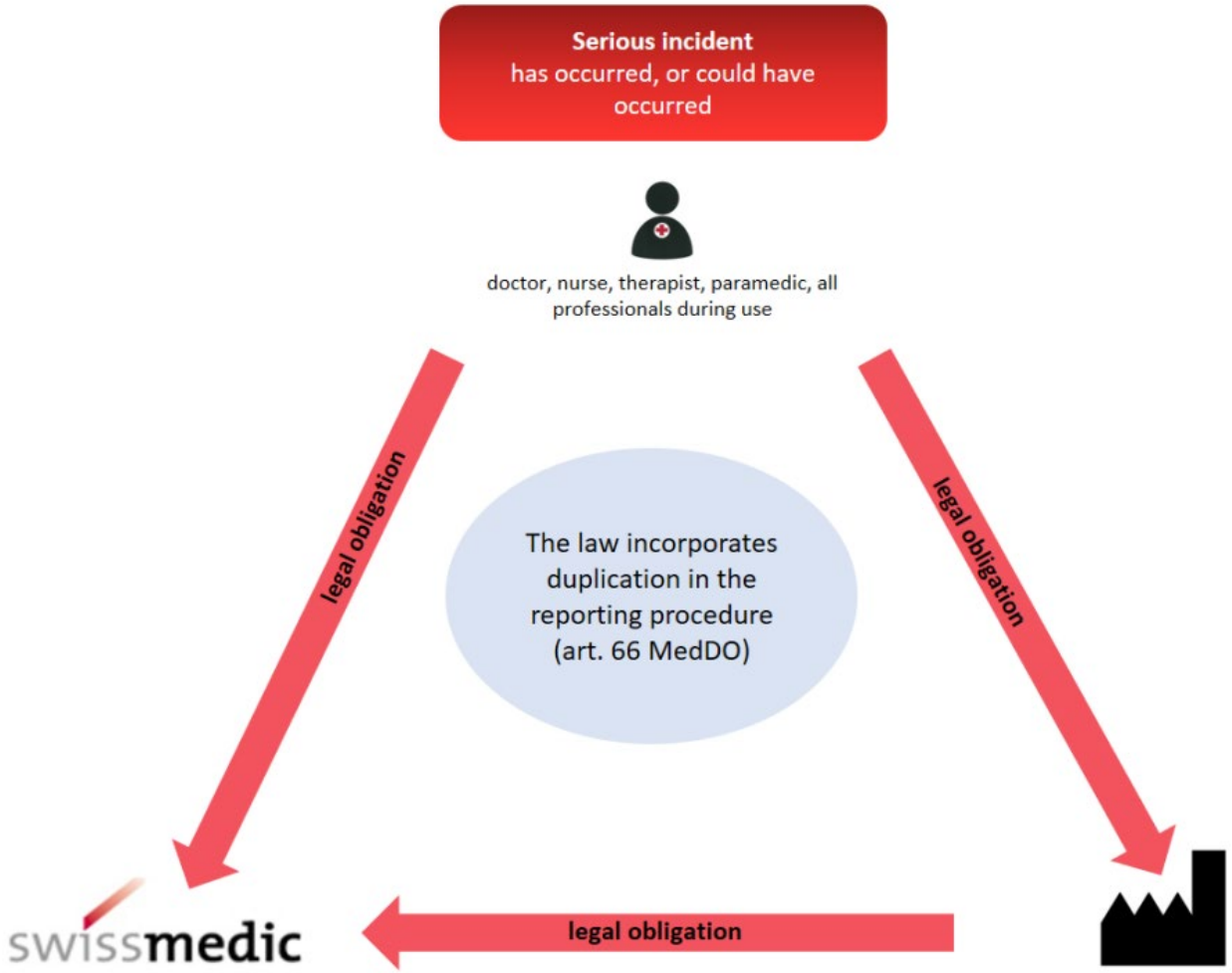
Reporting obligations and timelines

Any professional who becomes aware of a serious incident must report this to **the supplier and Swissmedic**. The report may be submitted by a professional association.
(Art. 66 para. 4 MedDO)

Important:
The reporting obligation concerns **all** serious incidents, i.e. including side effects!

Time limits:
2, 10 and 15 days (Art. 66 para. 4 MedDO in conjunction with Art. 87 MDR)

Reporting obligations, Duplication in the law



The role of the hospital according to MedDO

Provisions of criminal law

Art. 87 para. 1 let. c TPA

A fine not exceeding 50,000 Swiss francs shall be imposed on any person who wilfully:

violates an obligation under this Act to notify, register or disclose;

Art. 87 para. 3 TPA

If the person concerned acts through negligence, the penalty shall be a fine not exceeding 20,000 Swiss francs.

Art. 78 MedDO: **Duty to cooperate and provide information**

Economic operators that place a device **on the market** in Switzerland or in a contracting state, and economic operators, **professionals and healthcare institutions** that make a device available on the market or put it into service in Switzerland or a contracting state have a duty to cooperate on matters of enforcement. In particular, they must provide, free of charge, all necessary information and all necessary proof and documentation to the enforcement bodies.

Who counts as a professional?

Definition in Art. 59 para. 3 TPA: Reporting obligation for **professional users**

Annex 2 MedDO
Professional = healthcare professional (expression used in MDR)

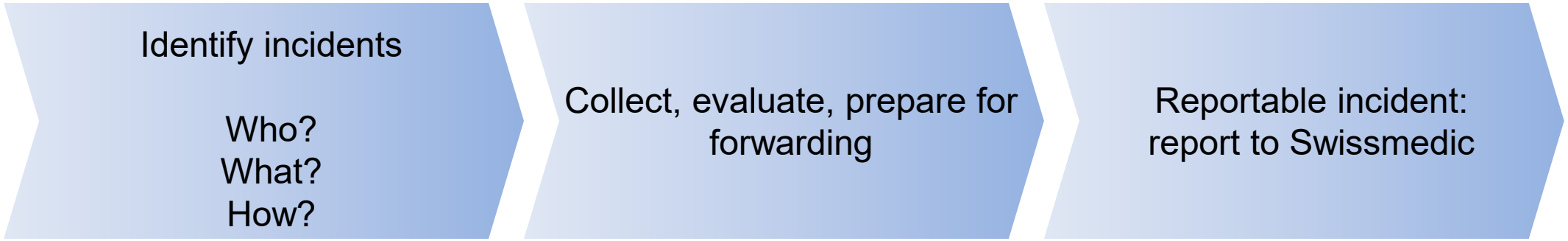
The term "professional" can be used to differentiate it from the definition of "lay person" (Art. 2 point 38 MDR)
Professional = "a person who has **formal education** in the relevant field of **healthcare or medical discipline**".

The role of the hospital

For reports according to Article 66 paragraph 4 (reporting obligation for professionals), the hospitals set up an internal reporting system within the framework of an established quality management system.
(Art. 67 para. 1 MedDO)

They must designate a suitable competent person (vigilance contact person) with a medical or technical qualification to assume responsibility for reporting to Swissmedic. They must supply this person's contact details to Swissmedic.
(Art. 67 para. 2 MedDO)

Materiovigilance process in the hospital



The role of the hospital

Records and all documents created under the vigilance quality management system must be retained for at least 15 years.

(Art. 67 para. 3 MedDO)

Requirements for reporting, information

- Trade name of the device
- Name and address of the manufacturer
- Name and address of the supplier
- Lot number LOT
- Serial number SN
- UDI (Unique Device Identification) Code (if it exists)

(01)24531543215315 (17)255612(10)ABCD (21)F2445

- Precise description of the incident
- Actual and/or possible consequences (reason for classification as serious)

Report must be submitted **electronically** in **machine-readable** form, **as specified by Swissmedic** (Art. 66 para. 5 MedDO)

Implementation of an FSCA

In hospital:

→ ensure that the action defined by the manufacturer is implemented

- the hospital is informed by the manufacturer/supplier and Swissmedic (via the vigilance contact person for medical devices) about the FSCA
- defined process
- traceability
- confirmatory feedback to the manufacturer/supplier as soon as the FSCA has been implemented

(Due diligence Art. 3 TPA, Maintenance Art. 71 MedDO, Reprocessing Art. 72 MedDO)

Provisions of criminal law:

Art. 86 para. 1 let. d TPA

A custodial sentence not exceeding three years or a monetary penalty shall be imposed on any person who wilfully:

d. places on the market, exports or uses medical devices which do not satisfy the requirements of this Act, or uses medical devices without the necessary technical or operational requirements being fulfilled;

Take-home messages

- **Professionals** are obliged to report serious incidents
- Supplier and Swissmedic must be informed of the serious incident

- Swissmedic has supplied **forms** for reporting serious incidents

- **Hospitals** must set up an internal reporting system within the framework of an established quality management system
- In the hospital, a v**igilance contact person** must be designated for submitting the reports to Swissmedic
- Hospitals must implement **FSCAs** so that the conformity of the devices is ensured

Monitoring tasks at Swissmedic

- Swissmedic is responsible for **monitoring vigilance** (Art. 76 para. 1 let. b MedDO)

- The **confidentiality of data** and the specific data that may be recorded and processed is regulated by law (Art. 62 and 62a TPA and Art. 79 MedDO)

- Swissmedic shall operate a **medical devices information system**, in particular to ensure the safety of medical devices, as well as vigilance and surveillance (Art. 62c TPA)

- Exchanging information with EU authorities and other authorities is possible subject to certain conditions (secrecy, to avert an immediate and serious risk to human life or health) (Art. 64 TPA, Art. 93 para. 11 MDR)
  - Art. 64 para. 3 TPA lists the specific data that may be disclosed in particular: results of market surveillance, inspection reports, information on clinical trials, information from vigilance, information on authorisations, information on conformity assessment bodies.

Thank you for your valued attention

Laws and ordinances mentioned in the presentation

MedDO	Medical Devices Ordinance (MedDO) of 1 July 2020 (version: 26 May 2021), SR 812.213
TPA	Federal Act on Medicinal Products and Medical Devices (Therapeutic Products Act, TPA) of 15 December 2000 (version: 26 May 2021), SR 812.21
MDR	REGULATION (EU) **2017/745** OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No. 178/2002 and Regulation (EC) No. 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC