swissmedic
20 Jahre 2002 - 2022

Vigilance and market surveillance

Obligations of economic operators, professionals, health institutions and laboratories

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1)

6 Schweiz FREITAG, 6. SEPT

HIV-Patientin trotz negativem Test weiterhin ansteckend

WINTERTHUR. Die HIV-Patientin Regina H. wurde im Spital als nicht mehr ansteckend getestet. Doch das stimmte nicht.

Die Patientin liess sich im Kantonsspital Winterthur testen. KEYSTONE

Regina H.*, seit 1992 HIV-positiv, lässt regelmässig ihre Virenlast überprüfen – wenn diese nicht nachweisbar ist, ist sie grundsätzlich nicht ansteckend. Für einen Test ging sie 2018 ins Kantonsspital Winterthur. Das Resultat war negativ. «Also haben mein Mann und ich uns entschieden, auf den Gummi zu verzichten», sagt sie. Eine spätere Untersuchung aber zeigte, dass Regina H. trotz des Testergebnisses ansteckend war. Ihr Arzt bestätigte dies. Für Regina H. ein Schock: «Mein Mann und ich haben uns in falscher Sicherheit gewiegt.» Sie geht davon aus, dass ihr Ehemann darum mit dem Virus infiziert wurde. Er wurde positiv getestet. Wann er sich genau angesteckt hat, bleibt offen.

Jürg Böni, Leiter des Nationalen Referenzzentrums für Retroviren, hat den Fall von Regina H. geprüft. Er kommt zum Schluss: «Es handelt sich um einen Einzelfall. Untersuchungen ergaben, dass der offiziell zugelassene Test nicht mangelhaft ist. In 99,9 Prozent der Fälle zeigt er ein richtiges Resultat an.» Deshalb werde der Test nicht aus dem Verkehr gezogen. Der Sprecher des Kantonsspitals sagt, dass dieses «permanent auf die Zuverlässigkeit seiner Labortests» achte. Und weiter: «Trotz modernster Laboratorien und sorgfältiger Auswertungen gibt es auch heute noch keine Gewähr, dass Tests mit hundertprozentiger Sicherheit funktionieren.»

Das Bundesamt für Gesundheit (BAG) wird nun in seinem Bulletin Empfehlungen veröffentlichen, damit sich der Fall nicht wiederholt. Sprecher Adrien Kay betont, dass der Test nicht zum allgemeinen Nachweis von HIV benutzt werde, sondern nur bei HIV-Patienten in Behandlung.

DÉSIRÉE POMPER/DANIEL WALDMEIER

*Name der Redaktion bekannt

2)

SWI swissinfo.ch Schweizer Perspektiven in 10 Sprachen

Kantone müssen Hunderttausende PCR-Speicheltests austauschen

▲ Bei längerer Lagerung und erhöhten Temperaturen kann es in den mangelhaften PCR-Testkits zu einer Vermehrung von Keimen in der Kochsalzlösung kommen. (Symbolbild) KEYSTONE/DPA-Zentralbild/WALTRAUD GRUBITZSCH sda-ats

Source:
1) Winterthur Cantonal Hospital: Test shows wrong result for HIV patient – 20 Minuten
2) Germ-infested PCR saliva tests – Blick

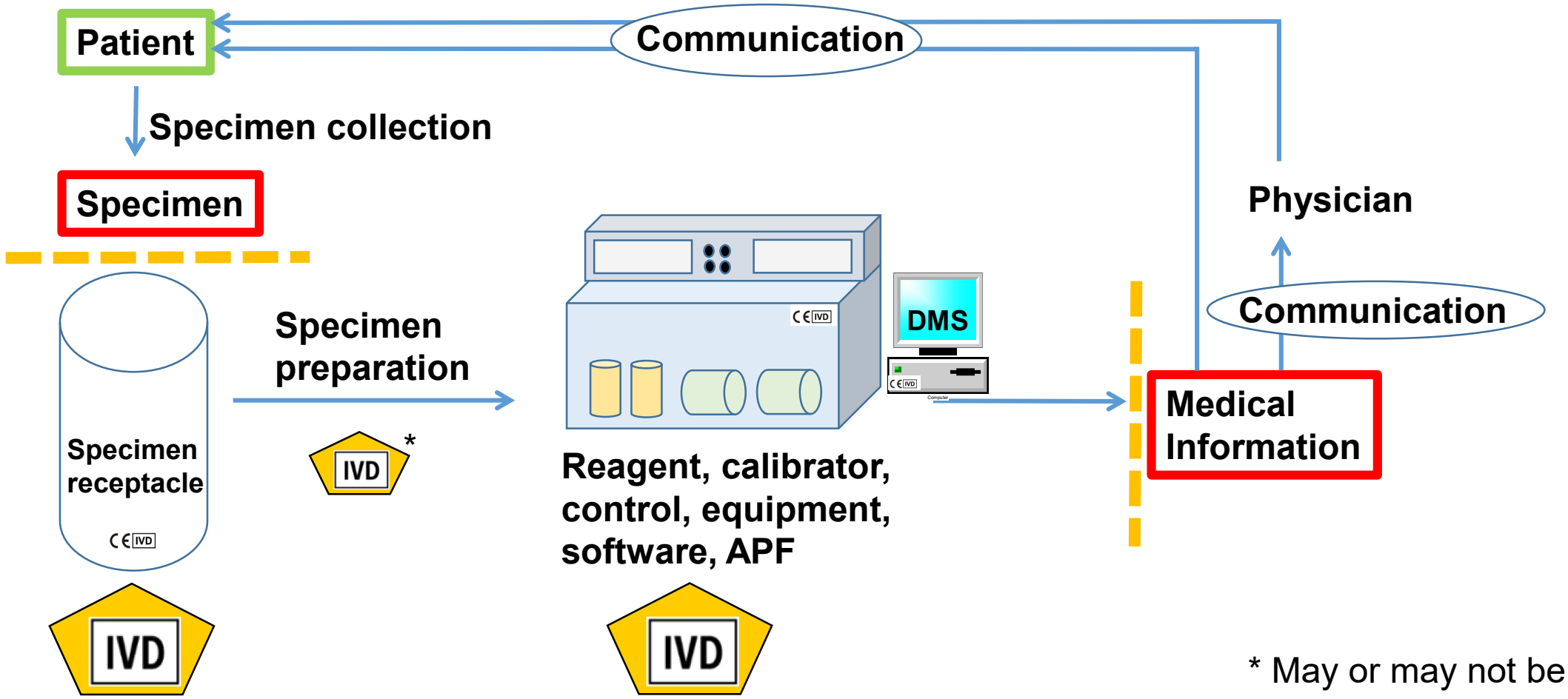
Agenda

1. Basics of IVDs and serious incidents
2. Duties of economic operators
3. Duties of professionals / health institutions / laboratories

What is an IVD?

- Medical device
- What does **in vitro** mean?
  - **“In glass”** (from Latin vitrum = glass).
  - Organisms and structures are not investigated in their natural environment / in the body, but...
  - under **experimental conditions** instead
- **Intended** for the in vitro examination of **specimens**, including blood and tissue donations, obtained **from the human body**
- For **clinical diagnosis** only (not for research use)

What is an IVD? Diagnosis logistics process



* May or may not be IVD depending on intended purpose

Take-home message (definition of IVD)

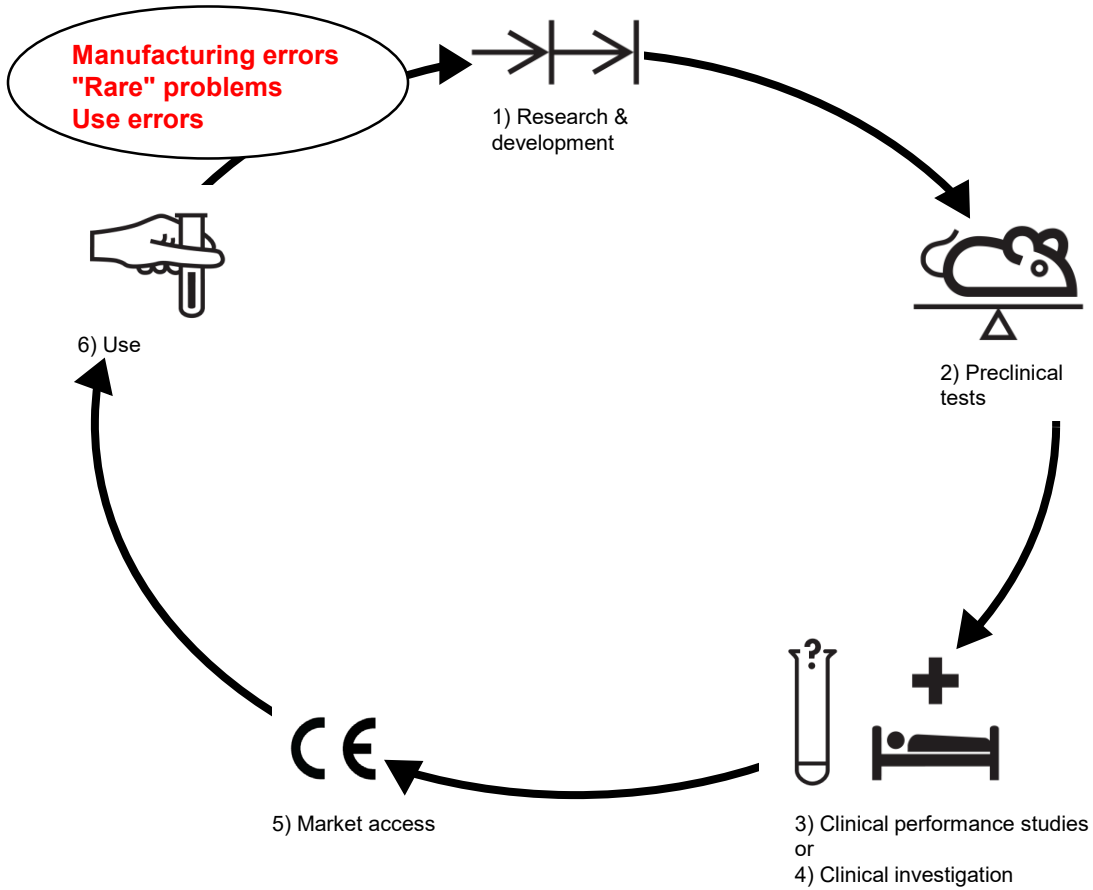
- (Simplified) definition:

  IVD = Medical device that generates medical information *in vitro* from specimens taken from humans

Specimen → 

→ Medical information

Why is reporting necessary?



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2) https://www.iso.org/obp/ui/#iso:grs:7000:3666
3) https://www.iso.org/obp/ui/#iso:grs:7000:3083
4) https://www.iso.org/obp/ui/#iso:grs:7001:PI_PF_002
5) https://www.fedlex.admin.ch/eli/cc/2001/520/en
6) https://www.iso.org/obp/ui/#iso:grs:7000:2715

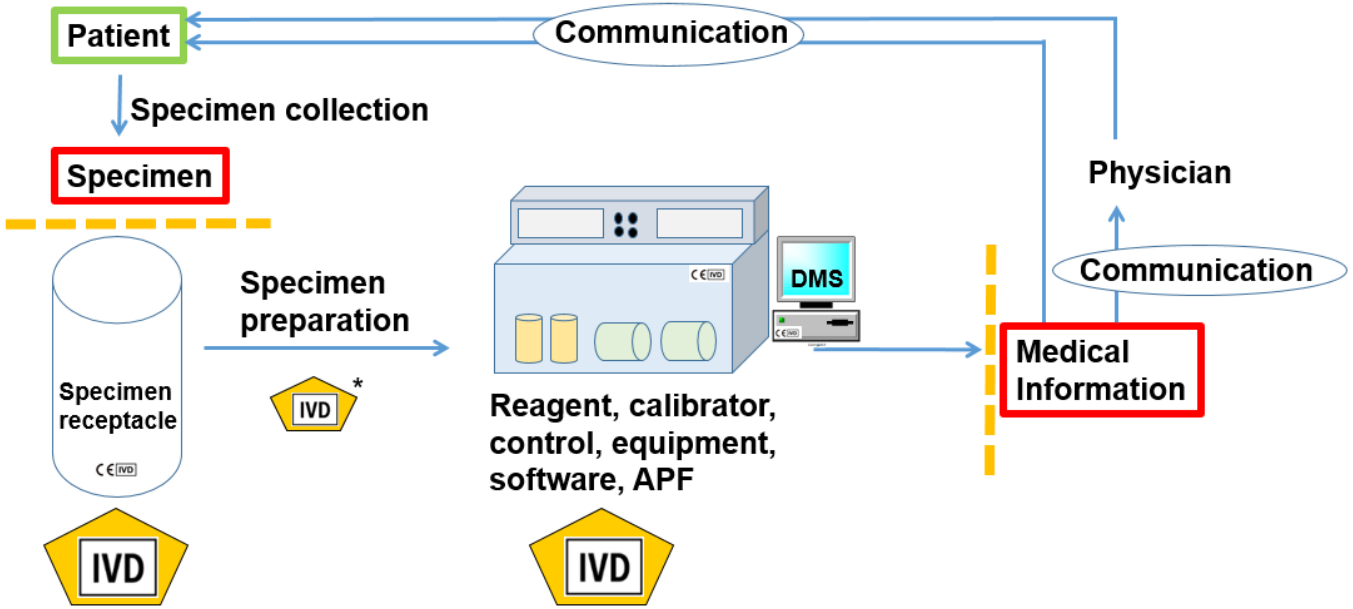
Incident

- **Malfunction**
- **Deterioration** in the characteristics or performance
- **Use-error** due to ergonomic features,
- Inadequacy of the **information** supplied
- **Harm** as a consequence of a medical decision, an action taken or not taken on the basis of information or results provided by the device

Serious incident

Incident that **directly or indirectly led, might have led or might lead** to any of the following:

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



Online question

- **Is a centrifuge an IVD?**
  - Yes
  - No
  - Depends on the intended purpose designated by the manufacturer

  ---

  - Answer: Depends on the intended purpose designated by the manufacturer

Online question

- **Does the following incident have to be reported? A customer reports that analytical results from an automated analyser have been assigned to the wrong patient codes. The results that have been incorrectly assigned are traceable.**
  - Yes
  - No

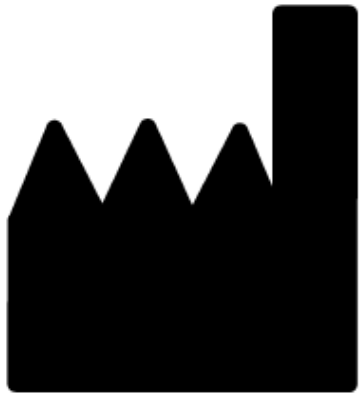
  - Answer: Yes (incorrect data assignment could have resulted in patients receiving the wrong diagnosis or treatment)

Take-home message

- **IVD**
  - "*Everything** between the specimen and the information"

- **Determining whether an incident is a serious incident:**
  - Does the definition of an incident apply?
  - Were there any serious consequences or might there have been or might there be if repeated?

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



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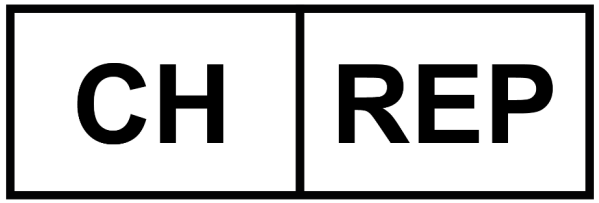

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3) https://www.iso.org/obp/ui#iso:grs:7000:3725
4) https://www.iso.org/obp/ui#iso:grs:7000:3724

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The following must be reported:

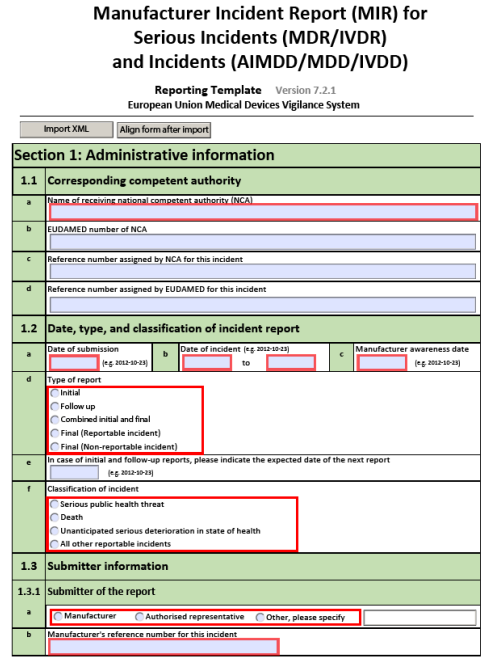
- **Every** serious incident
- Involving a device available on the market **in Switzerland**
- **Except** **expected erroneous results** that:
  - are **clearly documented** and **quantified** in the product information and technical documentation and
  - Are subject to trend reporting pursuant to Article 83 IVDR

Reporting serious incidents

- **Manufacturers** have to report to Swissmedic
- When a serious incident has occurred **in Switzerland**
- By MIR form via e-mail

Swiss authorised representatives:

- Swiss authorised representatives may also submit reports
- If they have access to the information required to complete the form (e.g. from the technical documentation)
- The representative is **responsible for reporting** serious incidents



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

Reporting serious incidents

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		

- When serious incidents are reported, Swissmedic will also check whether the manufacturer or authorised representative is registered in accordance with Art. 48 IvDO (**CHRN**) (spot checks)

Reporting serious incidents: Obligations of importers and distributors

- Obligation to **forward** to the manufacturer **without delay all reports** from the market
  - Reports: **Complaints and reports** from members of the healthcare professions, patients or users concerning **suspected incidents**
- Keeping a register / Collecting reports (“complaints list”)

Timelines

As a matter of principle: Report **as soon as the manufacturer becomes aware of incidents**

Specified maximum timelines: **2, 10, 15 days**

→**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 the event of **death** or an **unanticipated** serious deterioration in a person's state of health

→**15:** All other cases

Analysis of the serious incident

Principle:

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

Device investigation:

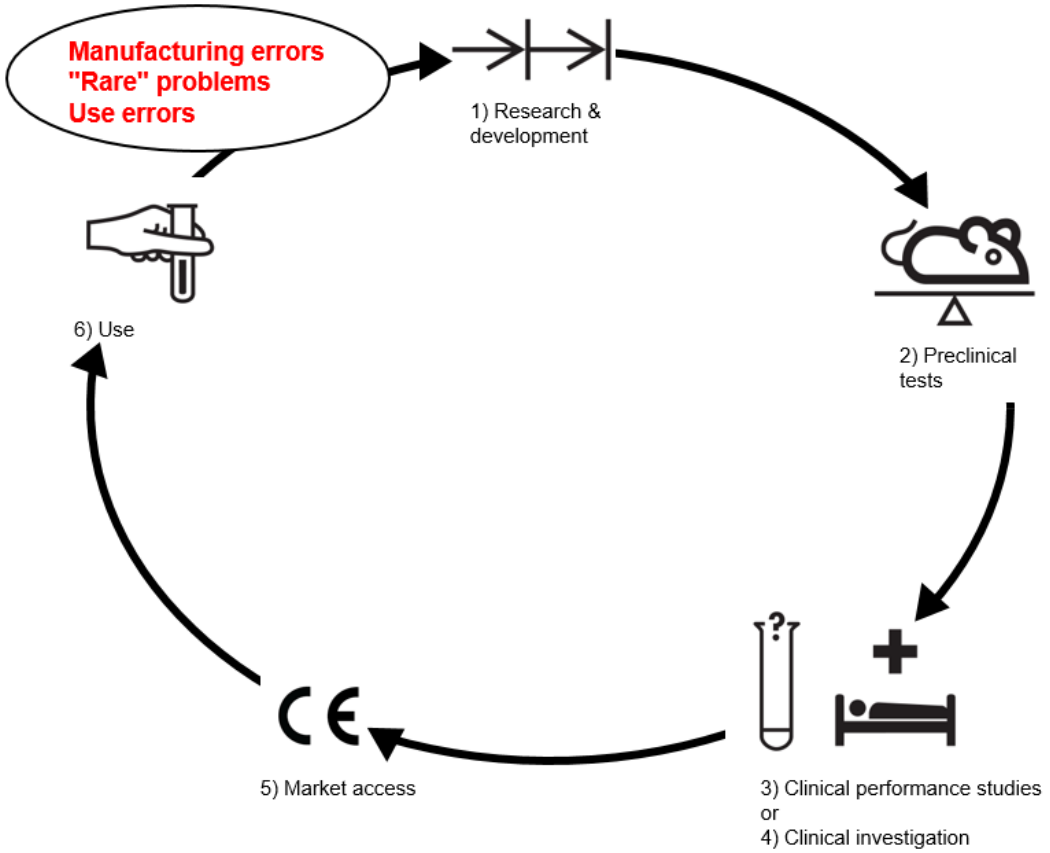
- Manufacturers must **not take any action** that could result in a change to the device or a sample from the affected batch if doing so could have an effect on the subsequent evaluation of the causes of the incident **before they have informed the responsible authority**.
- **Written notification to the authority** as part of the incident report stating that destructive investigation will start after 10 days if the authority has not replied by then.
- However, Swissmedic will not issue any official "release"

Field Safety Corrective Actions

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

Examples:

- Physical recall or exchange
- Modification to a device or its instructions for use
- Software update
- Notification to users to reduce the risk of a possible health threat

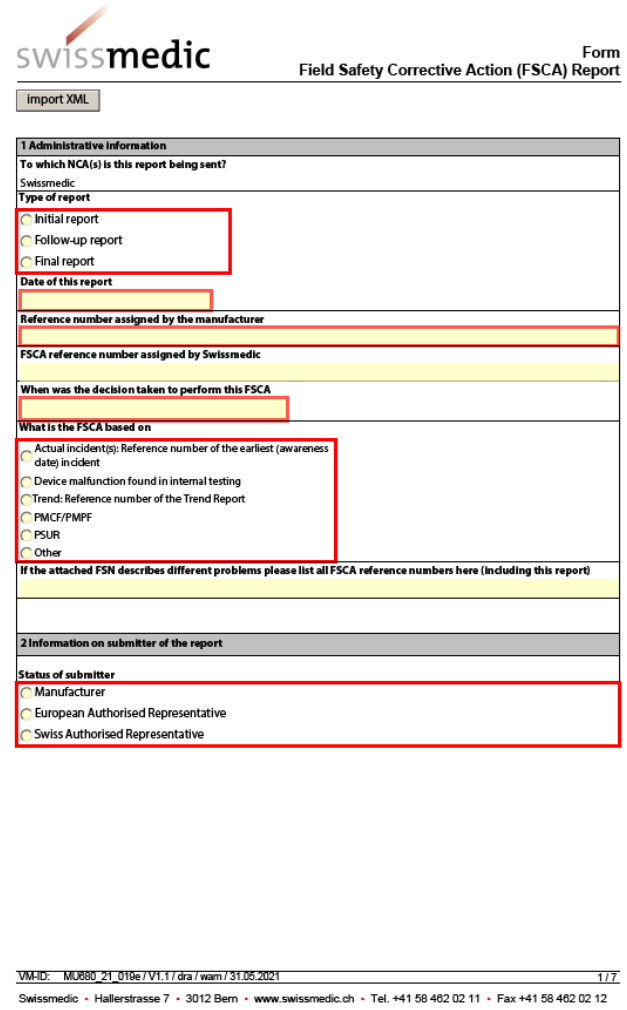


FSCA reporting obligations

- Report must be submitted by the **manufacturer**
- For every affected device in Switzerland
- By e-mail (specific CH-FSCA form, FSN, other information)

Swiss authorised representatives:

- Swiss authorised representatives may also submit reports
- If they have access to the information required to complete the form (e.g. from the technical documentation)
- The representative is responsible for reporting the FSCA to Swissmedic



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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: Manufacturers' obligations

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

- Art. 2 no. 30 IVDR defines a **user** as: Any healthcare professional or lay person who uses a device.

- Art. 22 para. 2 IVDR – the economic operator must be able to **identify**:
- Art. 47c para. 1 TPA – the economic operator must **disclose**:
  - Any economic operator to whom they have directly **supplied** a device
  - Any economic operator who has directly **supplied** a device to them
  - Any **healthcare institution or healthcare professional** to which/whom 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
- They must cooperate with manufacturers / authorised representatives and authorities in order to restore conformity or recall a device
- They must cooperate with manufacturers / authorised representatives to ensure traceability
- 10-year duty of disclosure

→ Hence the **duty of cooperation in implementing FSCAs**, e.g.

- Quarantine / no onward sale of devices that are still held by the importer/ distributor
- Procedure for recalls at the end customer
- Forwarding of information
- Implementation of measures on devices that are already on the market

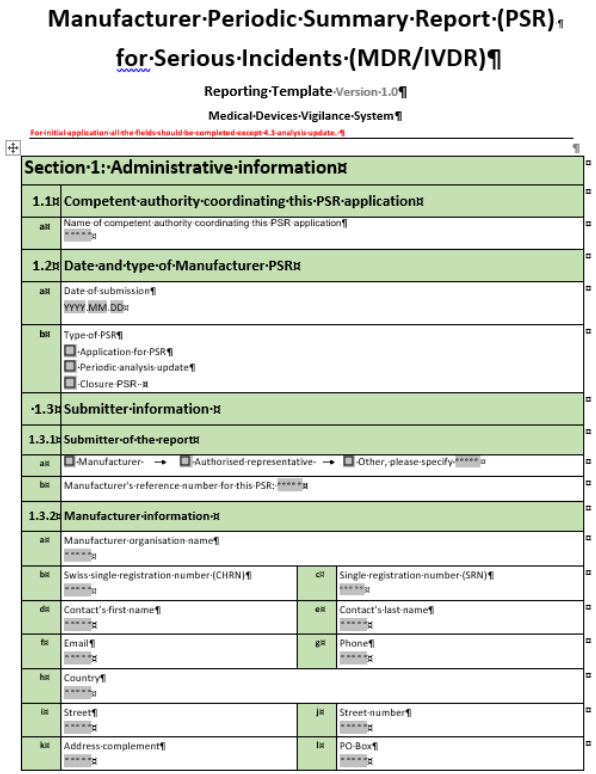
Periodic Summary Report

Conditions:

- Similar serious incidents with known root cause
- Covered by FSCA
- Serious incidents occur frequently and are 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: The CH authorised representative is responsible for reporting serious incidents involving devices produced by a foreign manufacturer



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)
d	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 Report

Reporting in the event of:

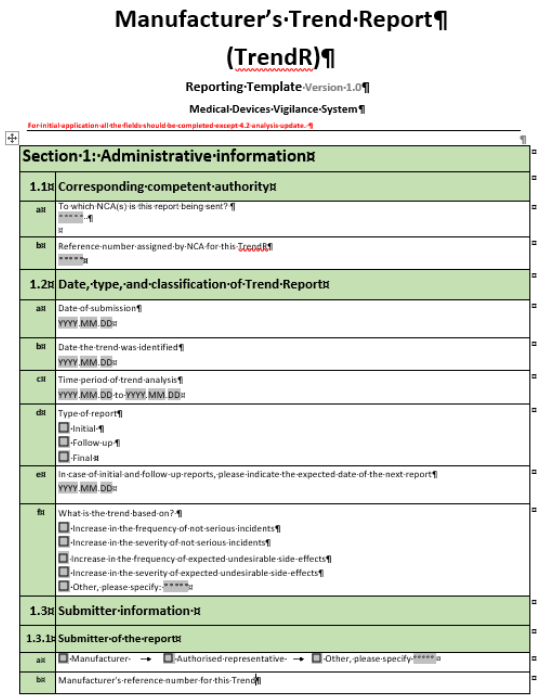
- A statistically significant rise in the frequency or severity of non-serious incidents

Involving:

- A significant impact on the risk-benefit analysis and
- Which results or might result in unacceptable risks to health or safety, or
- Which results or might result in a significant increase in expected inaccurate results in comparison to the device's declared performance.

Trend Report

- The **manufacturer or CH authorised representative** reports trends using the form or by e-mail
- Manufacturer must define the trend in its post-market surveillance plan:
  - Methodology for determining statistically significant increases in frequency or severity or a change in performance.



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

Periodic Safety Update Report and Post-Market Surveillance Report

Device class	Classes A and B:	Class C	Class D
Laws / ordinances	Art. 51 and 52 IvDO in conjunction with, Art. 79 and 80 IVDR	Art. 51 and 53–55 IvDO in conjunction with Art. 79 and 81 IVDR	Art. 51 and 53–55 IvDO in conjunction with Art. 79 and 81 IVDR
Post-market surveillance plan	Yes	Yes	Yes
Post-market surveillance (PMS) report	Yes	No	No
Safety report (Periodic Safety Update Report, PSUR)	No	Yes	Yes
Periodic update	As required	At least once a year	At least once a year
Submit to Designated Body	On request	Submit without prompting	Submit without prompting
Written review outcome by Designated Body	No	No	Review by Designated Body, which determines the outcome of its review with details of any action taken
Submit to Swissmedic	On request	On request	On request with Designated Body's review outcome

Obligation under IvDO

Art. 71 IvDO: **Duty to cooperate and provide information**

Economic operators:

- That **place a device on the market** in Switzerland or in a contracting state,
- That **make a device available on the market** or **put a device into service** in Switzerland or in a contracting state
- Are **required to cooperate with enforcement activities**,
  - To provide **all necessary information** free of charge and
  - To surrender the necessary **evidence and documentation**.

Online question

- **Which economic operators have to report serious incidents or FSCAs to Swissmedic (there may be more than one correct answer)?**
  - Manufacturers
  - Importers
  - Distributors
  - Swiss authorised representatives

  - Answer: Manufacturers or Swiss authorised representatives are responsible for compliance with reporting obligations

Online question

- **Can an importer or distributor decide for themselves which incident reports they forward to the manufacturer?**
  - Yes
  - No

  - Answer: No. They help collect all incidents and all incidents must be forwarded.

Take-home message

- **Manufacturers** or **Swiss authorised representatives** are responsible for compliance with the reporting obligations

- **Importers or distributors** help collect all incidents and **all incidents** must be forwarded.

- The **forms** provided by Swissmedic for reporting serious incidents, PSRs, trends and FSCAs must be used.

3. Duties of professionals, healthcare institutions and laboratories

Reporting obligations and timelines

Professionals

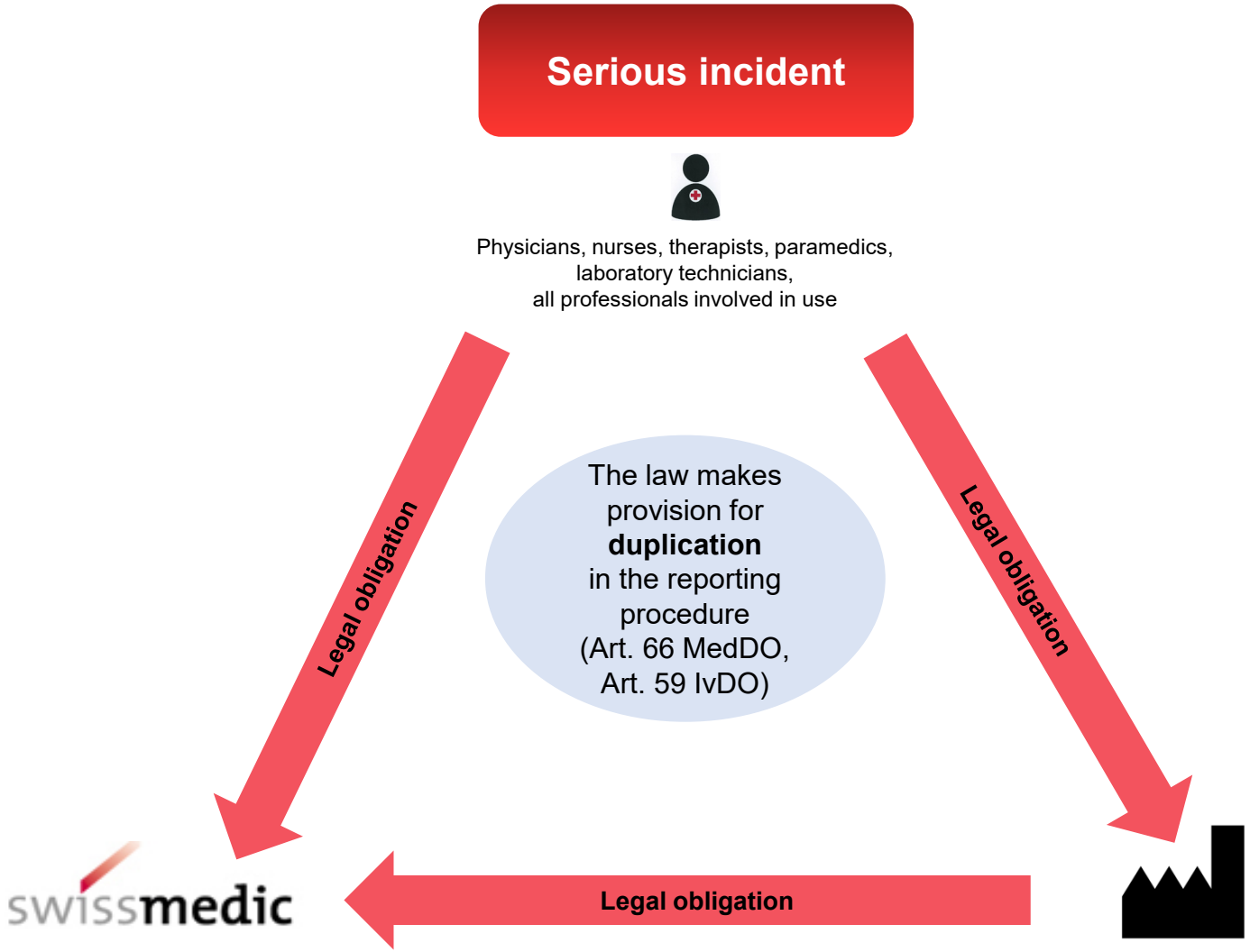
- Serious incidents that occur while a device is being used must be reported to the **supplier and Swissmedic**.
- The report may be submitted by a professional association.

- The reporting obligation applies to **all** serious incidents involving IVDs, **including Devices manufactured and used in healthcare institutions** (in-house IVDs).

Time limits:

- 2, 10 and 15 days

Reporting obligations, Duplication in the law



Who counts as a “professional”?

Definition in Art. 59 para. 3 TPA: Reporting obligation for **professional users**
In accordance with Art. 59 para. 4 IvDO: Reporting obligation for **professionals**

Annex 1 IvDO (difference only in German and Italien)
Healthcare professional (expression used in IVDR and IvDO)

The term “**healthcare professional**" can be used to differentiate it from the definition of "lay person" (Art. 2 point 31 IVDR)
Healthcare professional = "a person who has **formal education** in the relevant field of **healthcare or medical discipline**".

Professionel: Person who professionally uses products in their field of expertise.

→ **Professionals** therefore include members of the nursing professions, laboratory technicians and medical technicians in hospitals, for example.

Direct use by professionals

Art. 63 IvDO
Any professional who **uses** a **device** from a foreign country without placing it on the market **is responsible for the conformity of that device**.

→ Compliance with the obligation to report serious incidents under Art. 59 para. 4 IvDO must be ensured
→ Measures resulting from FSCAs must be implemented
→ It is possible that Swissmedic may **NOT** be notified of problems with the device
  → FSCAs are not published on the Swissmedic website
  → Associated enquiries cannot be answered

Duty to cooperate and provide information

Art. 71 IvDO

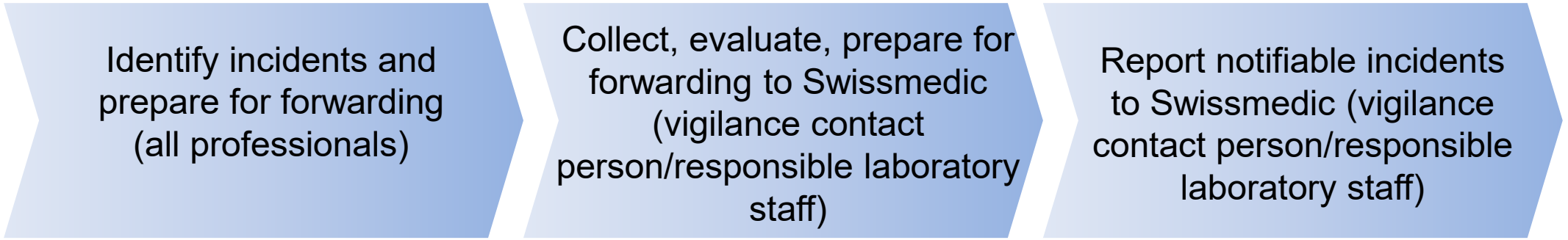
Professionals and healthcare institutions

- That **make a device available on the market** or **put a device into service** in Switzerland or in a contracting state
- Are **required to cooperate with enforcement activities**,
  - To provide **all necessary information** free of charge and
  - To surrender the necessary **evidence and documentation**.

Hospitals

- Hospitals must set up an internal reporting system within the framework of an established quality management system.
- 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.
- Records and all documents created under the vigilance quality management system must be retained for at least 15 years.

Materiovigilance process



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 available)

(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**

Implementation of an FSCA

→ Ensure that the action defined by the manufacturer is implemented
→ To guarantee device conformity

→ How do you achieve this?

- Manufacturer/supplier must inform device users
- Swissmedic informs:
  - On the Swissmedic website
  - Vigilance contact persons at hospitals (weekly)
  - Recipients on Swissmedic's e-mail distribution list (weekly)
- Define the process for implementation
- Device traceability by **recording UDI**
  - Mandatory in healthcare institutions: The list of in vitro diagnostic medical devices that healthcare institutions are required to store and keep is specified in implementing acts of the European Commission.
- Confirmatory feedback to the manufacturer/supplier as soon as the FSCA has been implemented

Online question

- **Which users have to report serious incidents to Swissmedic (there may be more than one correct answer)?**
  - Patients
  - Laboratory technicians
  - Doctors
  - Cleaners
  - Vigilance contact persons

  - Answer: Professionals using the device (laboratory technicians, doctors), vigilance contact persons

Online question

- **Where can you find information on FSCAs (there may be more than one correct answer)?**
  - On the Swissmedic website
  - Weekly publication information from Swissmedic (e-mail)
  - Manufacturers are obliged to report them

  - Answer: All three are correct

Take-home message

- **Professionals** are obliged to report serious incidents
- Suppliers and Swissmedic must be informed of serious incidents
- Swissmedic has supplied **forms** for reporting serious incidents
- Hospitals must designate a **contact person** to submit the reports to Swissmedic
- Implement **FSCAs** to ensure device conformity

Useful links

Reporting incidents & FSCAs:

Reporting incidents & FSCAs (vigilance) (swissmedic.ch)

- Economic operators:

Economic operators (swissmedic.ch)

- Professionals and healthcare institutions / laboratories

Users (swissmedic.ch)

Procurement in health institutions:

Procurement (swissmedic.ch)

Laws and ordinances mentioned in the presentation

IvDO	Ordinance of 4 May 2022 on In Vitro Diagnostic Medical Devices (version of 26 May 2022), SR 812.219
MedDO	Medical Devices Ordinance of 1 July 2020 (Status as of 26 May 2022), SR 812.213
TPA	Federal Act on Medicinal Products and Medical Devices (Therapeutic Products Act, TPA) of 15 December 2000 (version of 1 January 2022), SR 812.21
IVDR	REGULATION (EU) **2017/746** OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU