Zāļu valsts aģentūra

Aktualitātes medicīnisko ierīču vigilances jomā

Vilnis Zvirbulis

Medicīnisko ierīču nodaļas vecākais eksperts

14.12.2023., Rīga

Kādi ir Zāļu valsts aģentūras uzdevumi medicīnisko ierīču vigilances un pēc tirgus uzraudzības jomā?

Zāļu valsts aģentūras uzdevumi

Nopietnu negadījumu izmeklēšanu, ko veic medicīnisko ierīču vai *in vitro* medicīnisko ierīču ražotāji, **pārraudzība** un **risku izvērtējums**, kas izriet no nopietnajiem negadījumiem, par kuriem ir paziņots.

Zāļu valsts aģentūras uzdevumi

- Ražotāja **ziņojumu par tendencēm izvērtēšana**
- **Periodisko apkopojošo ziņojumu izvērtēšana**
- **Vigilances datu analīze**

Zāļu valsts aģentūras uzdevumi

- Dalība informācijas **koordinētā izvērtēšanas procedūrā** par nopietniem negadījumumiem vai par operatīvajām koriģējošajām drošības darbībām

- Dalība Medicīnisko ierīču koordinācijas grupas darba apakšgrupā ***"Pēc tirgus uzraudzība un vigilance"*** *(group MDCG - Post-Market Surveillance and Vigilance - PMSV Working Group for NCA (National Competent Authorities))*

Zāļu valsts aģentūras uzdevumi

- ZVA tīmekļa vietnes uzturēšana **informācijas par saņemtajiem drošuma paziņojumiem** publiskošanai, kā arī elektroniskās sistēmas uzturēšana, lai **centralizēti valsts līmenī reģistrētu ziņojumus par negadījumiem** ar medicīniskajām ierīcēm.

Medicīnisko ierīču (turpmāk - *MI*) un *In Vitro* diagnostisko medicīnisko ierīču (turpmāk - *IVD MI*) pēc tirgus uzraudzības un vigilances dokumentu kopums

Pēc tirgus uzraudzība

Ražotāja ziņojums par operatīvām koriģējošām darbībām
Field Safety Corrective Action Report Form (FSCA);

Ražotāju periodiskie atjauninātie drošuma ziņojumi
Periodic safety update report (PSUR);

Ražotāju operatīvie drošuma paziņojumi
Field Safety Notice (FSN);

Pēc tirgus uzraudzības ziņojums
Post-market surveillance report (PSR).

Vigilance

1) Ražotāja ziņojums par nopietniem negadījumiem

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

2) Ražotāja ziņojums par tendencēm

Trend Report;

3) Ražotāja periodiskais apkopotais ziņojums

Periodic summary report (PSR);

Ražotāja tendenču ziņojums (Trend Report)

European Commission
https://ec.europa.eu › renditions › pdf

Report Form Manufacturer's Trend Report

2018. gada 6. nov. — Report **Form**. Manufacturer's **Trend Report**. Medical Devices Vigilance System. (MEDDEV 2.12/1 rev 7) v.12/11. 1. Administration Information.

Report Form
Manufacturer's Trend Report

Medical Devices Vigilance System
(MEDDEV 2.12/1 rev 7)

v.12/11

1. Administration Information
Recipient (Name of National Competent Authority NCA)
Address of National Competent Authority
Date of this report
Reference number assigned by the manufacturer
Reference number assigned by NCA
Type of report ☐ Trend Initial ☐ Trend Follow up ☐ Trend Final
Do these incidents / trend represent a serious public health threat? ☐ Yes ☐ No
Identify to what other NCAs this report was **also** sent
2. Information on submitter of the report
Status of submitter ☐ Manufacturer ☐ Authorised Representative within EEA, Switzerland and Turkey ☐ Others: (identify the role) :
3. Manufacturer information
Name

Ražotāja periodiskais apkopotais ziņojums
Periodic summary report (PSR)

Manufacturer's Periodic Summary Report (PSR)
Medical Devices Vigilance System (MEDDEV 2.12/1 rev 7)

v.12/11

1. Administration Information
To which NCA(s) is this report being sent?
Date of this report
Reference number assigned by the manufacturer
Reference number assigned by NCA
Type of report ☐ Initial report ☐ Follow up report Follow up Number s ☐ Final report

2. Information on submitter of the report
Status of submitter ☐ Manufacturer ☐ Authorised Representative within EEA, Switzerland and Turkey ☐ Others: (identify the role) :

3. Manufacturer information	
Name	
Contact name	
Address	
Postcode	City
Phone	Fax
E-mail	Country

4. Authorised Representative information
Name
Contact name

Ražotāja ziņojums par nopietniem negadījumiem

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

- MIR

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

Reporting Template Version:7.3.0

European Union Medical Devices Vigilance System

Section 1: Administrative information

1.1 Responsible competent authority in which country the incident occurred

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 report submission in format YYYY-MM-DD	b	Date of incident in format YYYY-MM-DD to
c	Manufacturer awareness date of the incident in format YYYY-MM-DD	d	Manufacturer awareness date of reportability in format YYYY-MM-DD

e Type of report

- ◯ Initial
- ◯ Follow up
- ◯ Combined initial and final
- ◯ Final (Reportable incident)
- ◯ Final (Non-reportable incident)

f In case of initial and follow-up reports, please indicate the expected date of the next report in format YYYY-MM-DD

g Classification of incident

3.4	Initial reporter		
a	Role of initial reporter ◯ Healthcare professional ◯ Patient ◯ Lay user ◯ Other, please specify		
b	Name of healthcare facility where incident occurred		
c	Healthcare facility report number (if applicable)		
d	Contact's first name	e	Contact's last name
f	Email	g	Phone
h	Country ☐ if other, please specify		
i	Street	j	Street number
k	Address complement	l	PO Box
m	City name	n	Postal code

Manufacturer Incident Report (MIR) for Serious Incidents (MDR/IVDR)

Reporting Template Version: 7.3.1

European Union Medical Devices Vigilance System

Import XML | Align form after import

Section 1: Administrative information

1.1 Responsible competent authority in which country the incident occurred

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 report submission in format YYYY-MM-DD	b	Date of incident in format YYYY-MM-DD to
c	Manufacturer awareness date of the incident in format YYYY-MM-DD	d	Manufacturer awareness date of reportability in format YYYY-MM-DD

e Type of report

- ○ Initial
- ○ Follow up
- ○ Combined initial and final
- ○ Final (~~Reportable~~ Serious incident)
- ○ Final (Non-reportable incident)

f In case of initial and follow-up reports, please indicate the expected date of the next report in format YYYY-MM-DD

g Classification of serious

4.2	Cause investigation and conclusion
a	**For Final (~~Reportable~~ Serious incident):** Description of the manufacturer's evaluation concerning possible root causes /causative factors and conclusion
b	**~~For Final (Non-reportable incident):~~** ~~Fill out rationale for why this is considered not reportable~~
c	Is root cause confirmed? ◯ Yes ◯ No Suspicion or confirmation of a relationship between the ~~reportable~~ serious incident and the medicinal substance(s) / product(s), tissue (s), cell(s) of human origin or their derivative(s) associated with the device? ◯ Yes ◯ No
d	Has the risk assessment been reviewed ? ◯ Yes ◯ No If 'No', rationale for no review required:

Negadījumu izvērtēšanas piemēri MIR ziņojumos

Nokavēts ziņojuma iesniegšanas termiņš

1.2	Date, type, and classification of incident report					
a	Date of submission 2023-10-02 (e.g. 2012-10-23)	b	Date of incident (e.g. 2012-10-23) 2023-06-05 to 2023-06-05	c	Manufacturer awareness date 2023-09-27 (e.g. 2012-10-23)	
d	Type of report ● Initial					

1.2	Date, type, and classification of incident report					
a	Date of submission 2023-11-01 (e.g. 2012-10-23)	b	Date of incident (e.g. 2012-10-23) 2023-06-05 to 2023-06-05	c	Manufacturer awareness date 2023-09-27 (e.g. 2012-10-23)	
d	Type of report o Initial o Follow up o Combined initial and final ● Final (Reportable incident) o Final (Non-reportable incident)					

Ražotājam nav zināmi MI ID-parametri:

b	Nomenclature text/Description of the device and its intended use 46920		
c	Model Nova T	d	Catalogue/reference number
e	Serial number	f	Lot/batch number not available
g	Software version	h	Firmware version
i	Device manufacturing date (e.g. 2012-10-23)	j	Device expiry date (e.g. 2012-10-23)
k	Date when device was implanted (e.g. 2012-10-23) 2022-12-30 to 2022-12-30	l	Date when device was explanted (e.g. 2012-10-23) 2023-06-08 to 2023-06-08

MIR iztrūkst ĀI nosaukums, kaut arī negadījuma apraksts norāda, ka NEGADĪJUMĀ IR CIETIS PACIENTS. MI nav saglabāta

3.1	Nature of incident
a	Provide a comprehensive description of the incident, including (1) what went wrong with the device (if applicable) and (2) a description of the health effects (if applicable), i.e. clinical signs, symptoms, conditions as well as the overall health impact (i.e. Death; life-threatening; hospitalization – initial or prolonged; required intervention to prevent permanent damage; disability or permanent damage; congenital anomaly/Birth defects; indirect harm; no serious outcome)

This spontaneous case was reported by a physician and describes the occurrence of UTERINE PERFORATION ("Complete uterine perforation") and PARAMETRIC ABSCESS ("IUD in right parametrium with abscessus") in a 31 year-old female patient who had [redacted] intrauterine device inserted (lot no. not available) for contraception. Additional non-serious events are detailed below.

The patient had a MEDICAL HISTORY of Parity 2 (last delivery on 12-NOV-2022, no c-sections) and Gravida II. No previous IUD used. No abnormal uterine findings prior to insertion. IUD insertion was easy, there were no complaints immediately after insertion. CONCURRENT CONDITIONS were listed as Postpartum state (6 weeks, 6 days at time of IUS insertion) since 12-NOV-2022 and Breast feeding (at time of IUS insertion).

On 30-DEC-2022, the patient h[redacted]
In February 2023 she experien[redacted] and
GENITAL HAEMORRHAGE ("b[redacted]
On 05-JUN-2023 she experien[redacted] ervention
required).
On 08-JUN-2023 she experien[redacted] rvention
required). [redacted] was rem[redacted] rgery
with IUS removal, salpingectom[redacted]

No causality assessment was r[redacted] L
HAEMORRHAGE, PELVIC PA[redacted]

The reporter commented: Samp[redacted]
satisfactory at time of report.
On 05-JUN-2023 patient prese[redacted]

DIAGNOSTIC RESULTS (norm[redacted]
Body mass index: 25.51 kg/sq[redacted]
[Computerised tomogram pelvis[redacted] glas
behind uterus and to the right
[Hysterometry] on 30-DEC-202[redacted]
[Laparoscopy] on 08-JUN-2023[redacted]
[Ultrasound scan] on 30-DEC-2[redacted] d in the
uterus; on 05-JUN-2023: Not p[redacted]

QUALITY-SAFETY EVALUATIO[redacted]
For [redacted]: No complaint sample was available.
The batch number is unknown, and therefore the batch documentation and retain samples could not be investigated. All batches met the set specifications at the time of release.

Ja MI/IVD MI nav saglabāta, tad NKI nevar izvērtēt ražotāja izmeklētās darbības.

c	What is the current location of the device? o Healthcare facility/carer o Distributor o Patient/user o Discarded o In transit to manufacturer o Remains implanted o Manufacturer ● Unknown o Other:

Situācijās, kad ražotājam nav pieejama negadījumā ietekmētā MI/ IVD MI, NKI nevar nodrošināt vigilances sistēmas prasības.

Section 3: Incident information derived from healthcare professional/facility/patient/lay user/other

3.1 Nature of incident

a **Provide a comprehensive description of the incident, including (1) what went wrong with the device (if applicable) and (2) a description of the health effects (if applicable), i.e. clinical signs, symptoms, conditions as well as the overall health impact** (i.e. Death; life-threatening; hospitalization – initial or prolonged; required intervention to prevent permanent damage; disability or permanent damage; congenital anomaly/Birth defects; indirect harm; no serious outcome)

It was reported that post implantation of [redacted]el breast prosthesis left side prosthesis ruptured. The ultrasound examination identified silicone deposits in the left side breast.

3.2 Medical device problem information

a **IMDRF Medical device problem codes (Annex A)**
Coding with IMDRF terms is a mandatory requirement.

	Choice 1 *(most relevant)*	Choice 2	Choice 3	Choice 4	Choice 5	Choice 6
IMDRF 'Medical device problem codes'	**Code** A0412	**Code**	**Code**	**Code**	**Code**	**Code**

If you think the incident is unique and a suitable IMDRF term is missing, briefly explain:

b **Number of patients involved**
1

c **What is the current location of the device?**

- ○ Healthcare facility/carer
- ○ Distributor/Importer
- ○ Patient/user
- ○ Discarded
- ○ In transit to manufacturer
- ○ Remains implanted
- ○ Manufacturer
- ◉ Unknown
- ○ Other

d **Operator of device at the time of the incident**

◉ Healthcare professional ○ Patient/lay user ○ Other, please describe

Situācija, ka ražotāja rīcībā nav datu par sākotnējo ziņotāju:

	symptoms, and conditions codes' (Annex E)	E1403	E2308			
	IMDRF 'Health impact' codes (Annex F)	Code F12	Code	Code	Code	Code	Code

If you think the incident is unique and a suitable IMDRF term is missing, briefly explain:

b	**Age of patient at the time of the incident** **years** **months** **days**		
c	**Gender** ◉ Female ○ Male ○ Unknown ○ Not applicable		
d	**Body weight (kg)**		
e	**List any of the patient's prior health condition or medication that may be relevant to this incident**		
3.4	**Initial reporter (can be healthcare professional of facility, patient, lay user)**		
a	**Role of initial reporter** ○ Healthcare professional ◉ Patient ○ Lay User ○ Other, please specify		
b	**Name of healthcare facility where incident occurred** Unknown		
c	**Healthcare facility report number (if applicable)**		
d	**Contact's first name** Unknown	e	**Contact's last name** Unknown
f	**Email**	g	**Phone** Unknown
h	**Country** LV - Latvia		
i	**Street**	j	**Street number**
k	**Address complement**	l	**PO Box**
m	**City name** Unknown	n	**Postal code** Unknown

Situācija, kad Ražotājs nesniedz ziņas par ārstniecības iestādi, jo sākotnējais ziņotājs ir izplatītājs:

Section 3: Incident information derived from healthcare professional/facility/patient/lay user/other

3.1 Nature of incident

a Provide a comprehensive description of the incident, including (1) what went wrong with the device (if applicable) and (2) a description of the health effects (if applicable), i.e. clinical signs, symptoms, conditions as well as the overall health impact (i.e. Death; life-threatening; hospitalization - initial or prolonged; required intervention to prevent permanent damage; disability or permanent damage; congenital anomaly/Birth defects; indirect harm; no serious outcome)

Reportable based on analyis completed on 16Nov2023

It was reported that during a procedure [redacted] catheter was selected for use, however, before re-sheathing to move to the right side veins, while working the Left inferior vein, the system stopped the ablation with the error message [redacted] Blood was detected in the catheter after deflation on the 7th application. All previous multiple applications were made on left-sided veins with difficult anatomy to occlude. In order to resolve the issue, the device was replaced, and the issue was resolved. No visible blood was observed in the catheter. The procedure was completed. No patient complications were reported.

However, analysis of the returned device revealed a breach in the outer balloon and blood within the balloon.

3.2 Medical device problem information

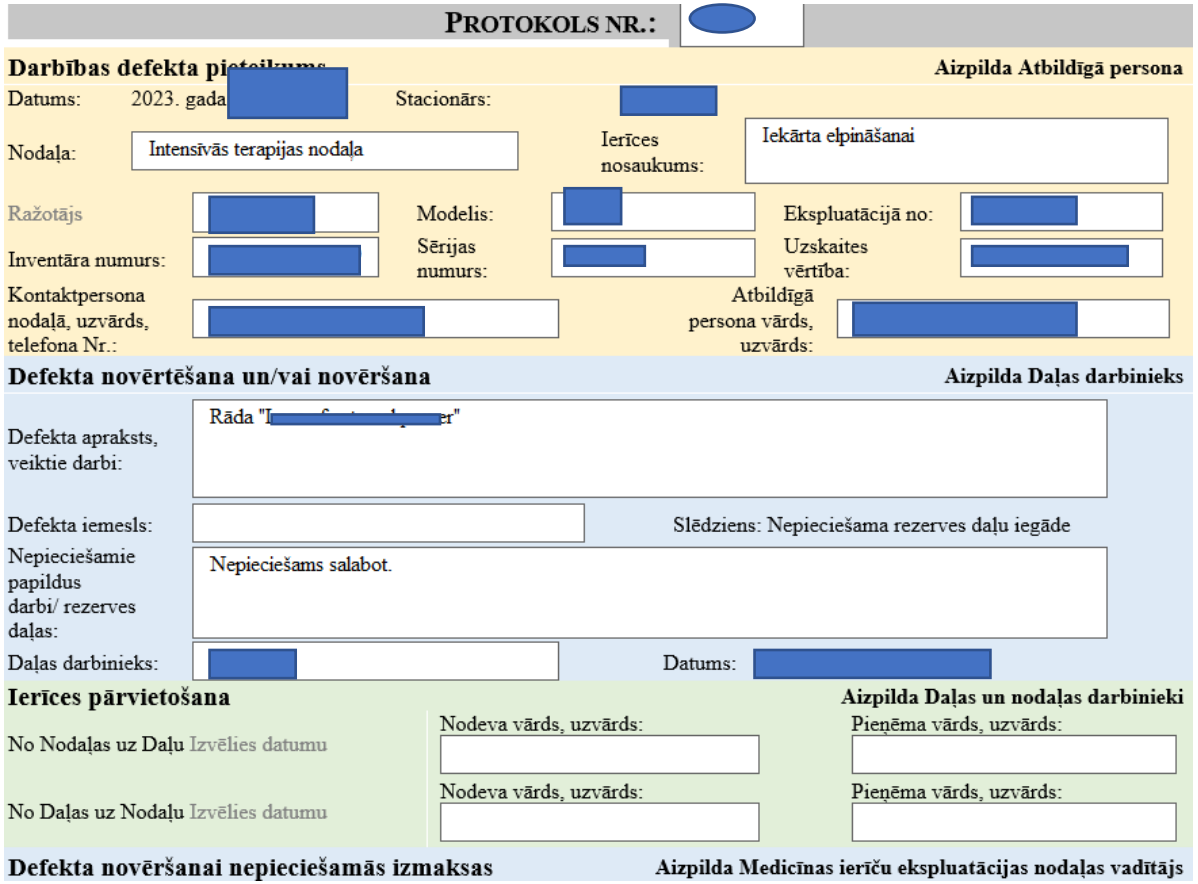
a IMDRF Medical device problem codes (Annex A)
Coding with IMDRF terms is a mandatory requirement.

	Choice 1 (most relevant)	Choice 2	Choice 3	Choice 4	Choice 5	Choice 6
IMDRF 'Medical device problem codes'	Code A180103	Code	Code	Code	Code	Code

3.4	**Initial reporter (can be healthcare professional of facility, patient, lay user)**
a	Role of initial reporter ☐ Healthcare professional ☐ Patient ☐ Lay user ☒ Other, please specify Distributor
b	Name of healthcare facility where incident occurred
c	Healthcare facility report number (if applicable)

Situācija, kad KI ir dati, ka ir notikusi sadarbība starp izplatītāju un ražotāju:

Pat ja ĀI nav iesniegusi signālziņojumu, MIR formai klāt pievienots protokols par notikušo negadījumu



PROTOKOLS NR.:

Darbības defekta pieteikums — **Aizpilda Atbildīgā persona**

Datums: 2023. gada [redacted] Stacionārs: [redacted]

Nodaļa: Intensīvās terapijas nodaļa

Ierīces nosaukums: Iekārta elpināšanai

Ražotājs [redacted] Modelis: [redacted] Ekspluatācijā no: [redacted]

Inventāra numurs: [redacted] Sērijas numurs: [redacted] Uzskaites vērtība: [redacted]

Kontaktpersona nodaļā, uzvārds, telefona Nr.: [redacted] Atbildīgā persona vārds, uzvārds: [redacted]

Defekta novērtēšana un/vai novēršana — **Aizpilda Daļas darbinieks**

Defekta apraksts, veiktie darbi: Rāda "[redacted]er"

Defekta iemesls:

Slēdziens: Nepieciešama rezerves daļu iegāde

Nepieciešamie papildus darbi/ rezerves daļas: Nepieciešams salabot.

Daļas darbinieks: [redacted] Datums: [redacted]

Ierīces pārvietošana — **Aizpilda Daļas un nodaļas darbinieki**

No Nodaļas uz Daļu Izvēlies datumu — Nodeva vārds, uzvārds: — Pieņēma vārds, uzvārds:

No Daļas uz Nodaļu Izvēlies datumu — Nodeva vārds, uzvārds: — Pieņēma vārds, uzvārds:

Defekta novēršanai nepieciešamās izmaksas — **Aizpilda Medicīnas ierīču ekspluatācijas nodaļas vadītājs**

Minētā ziņojuma iesniegšanas termiņi:

1.2	Date, type, and classification of incident report				
a	Date of submission 2023-10-16 (e.g. 2012-10-23)	b	Date of incident (e.g. 2012-10-23) 2023-10-03 to 2023-10-03	c	Manufacturer awareness date 2023-10-09 (e.g. 2012-10-23)

Minētā ziņojuma slēdziens:

4.2	Cause investigation and conclusion
a	**For Final (Reportable incident):** Description of the manufacturer's evaluation concerning possible root causes/causative factors and conclusion
	[redacted]s conclusion is the following: Root Cause: broken power supply. Correction: replacement of the power supply.
b	**For Final (Non-reportable incident):** Fill out rationale for why this is considered not reportable
c	Is root cause confirmed? (•) Yes ( ) No
d	Has the risk assessment been reviewed? (•) Yes ( ) No If 'No', rationale for no review required:
	If the risk assessment has been reviewed, is it still adequate? (•) Yes ( ) No Results of the assessment:

Zāļu valsts aģentūra

Vilnis Zvirbulis

Medicīnisko ierīču nodaļas vecākais eksperts

Vilnis.Zvirbulis@zva.gov.lv

14.12.2023., Rīga