MIS À JOUR LE 06/11/2024

How to declare if you are a manufacturer or distributor of medical devices

Consulter la version française

Post-market surveillance and vigilance

Manufacturers are required to submit vigilance reports to the ANSM for any incidents occurred in France involving medical devices, in accordance with Regulation (EU) 2017/745.
The manufacturer must also take appropriate safety action when required.
Further information about reporting adverse incidents and corrective actions to ANSMis available for manufacturers of medical devices.
We encourage manufacturers to use European Medical Device Nomenclature (EMDN).

Manufacturer Incident Report (MIR)

- Manufacturers should notify the ANSM of MIR using the MIRManufacturer Incident Report (MIR) form.
- Manufacturers should sent MIR (pdf and xml format) by mailbox:materiovigilance@ansm.sante.fr.
- To monitor the registration of MIR, manufacturers have an access via Vigimater to put ANSM’s reference.

Access to Vigimater

Field Safety Corrective Actions (FSCAs)

- Manufacturers should notify the ANSM of FSCA using theFSCA Report Form
- Manufacturers should sent FSCA by mailbox:materiovigilance@ansm.sante.fr

Trend report

- Manufacturers should notify the ANSM of trend report using theManufacturer’s Trend Report Form.
- Manufacturers should sent Trend Report by mailbox:materiovigilance@ansm.sante.fr.

Periodic Summary Report (PSR)

- Manufacturers should notify the ANSM of Periodic Summary Report using theManufacturer’s PSR Report Form.
- Manufacturers should sent PSR by mailbox:materiovigilance@ansm.sante.fr.

Documents

Reporting

- Manufacturer Incident Report (MIR) form

- Manufacturer incident report Helptext 2020
- FSCA Report Form
- Field safety notice template
- FSN customer reply
- FSN distributor/importer reply
- Manufacturer’s Trend Report Form
- ANSM requests medical device manufacturers who send out a field safety notice to place upon it the barcode of the involved devices
- Vigilance related of medical device (MD) or in vitro diagnostic medical devices (IVD) : Q&A on reading anomalies of the UDI carrier

Device Specific Vigilance Guidance (DSVG)

The following guidances provide additional informations to manufacturers that can assist them to identify incidents and complaints associated with specific medical device on reporting adverse incidents for different types of medical device:

- MDCG 2024-1 - Device Specific Vigilance Guidance (DSVG) Template
- MDCG 2024-1-1 - DSVG 01 on Cardiac ablation
- MDCG 2024-1-2 - DSVG 02 on Coronary stents
- MDCG 2024-1-3 - DSVG 03 Cardiac Implantable Electronic Devices (CIEDs)
- MDCG 2024-1-4 - DSVG 04 on Breast implants
- MDCG 2024-1-5 - DSVG 05 on Urogynaecological Surgical Mesh Implants used for Pelvic Organ Prolapse repair and Stress Urinary Incontinence
- DSVG 05 : Insulin Infusion Pumps and Integrated meter systems

+ All guidances are available on European Commission