MIS À JOUR LE 21/11/2024

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

Consulter la version française

Post-market surveillance and vigilance

Manufacturer is required to submit vigilance reports to the ANSM for any incidents occurred in France involving in vitro diagnostic medical devices, in accordance with Regulation (EU) 2017/746.
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 in vitro diagnostic 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:reactovigilance@ansm.sante.fr.
- To monitor the registration of MIR, manufacturers have an access viaVigimater 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:reactovigilance@ansm.sante.fr.

+ ANSM requests medical device manufacturers who send out a field safety notice to place upon it the barcode of the involved devices

Trend report

- Manufacturers should notify the ANSM of trend report using theManufacturer's Trend Report Form.
- Manufacturers should sent Trend Report by mailbox:reactovigilance@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:reactovigilance@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
- Vigilance related of medical device (MD) or in vitro diagnostic medical devices (IVD) : Q&A on reading anomalies of the UDI carrier