Role of the Competent Authority

Orthopaedica Belgica

Ostend

Thursday 25/04/2019

Ir. Christophe Driesmans

famhp federal agency for medicines and health products .be

Federal Agency for Medicines and Health Products

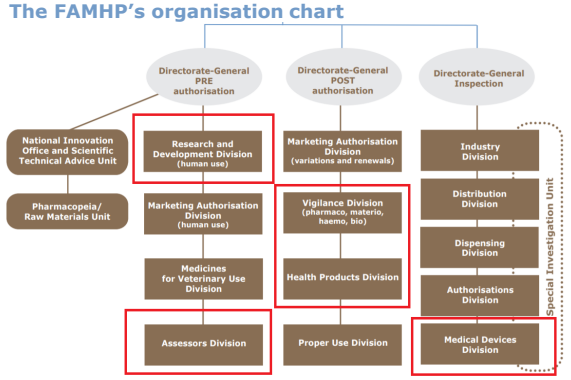
Established: 01/01/2007

Responsible Minister: Maggie De Block, Minister of Social Affairs and Public Health, and of Asylum and Migration

Role & Mission: The FAMHP is the Belgian competent authority in charge of ensuring the quality, safety and efficacy of medicines and health products from clinical development to use on the market and from collection to use in case of blood, cells and tissues.

Slogan: "Your medicines and health products are our concern"

The FAMHP's organisation chart



Serious implant failure

Often a **Serious Adverse Event** or **Incident**
=> reportable to FAMHP

Serious Adverse Event (SAE):
Non CE-marked device
Clinical investigation to obtain CE mark
=> R&D Division at FAMHP

Incident:
CE marked device
=> Vigilance Division (Materiovigilance entity) at FAMHP

Incident

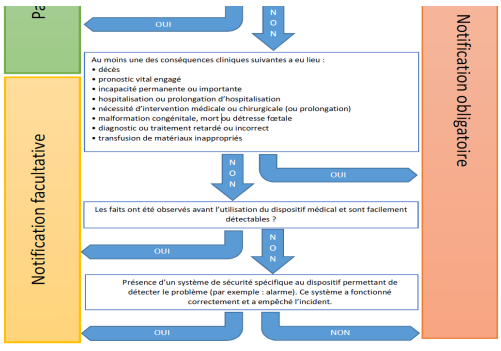
Definition used by FAMHP (meddev 2.12)

1. An event has occurred
2. The manufacturer's device is suspected to be a contributory cause of the incident
3. The event led, or might have led, to one of the following outcomes:
   - death of a patient, user or other person
   - serious deterioration in state of health of a patient, user or other person

FAMHP website:

- Decision tree to determine if event is incident or not

FAMHP Decision tree



Belgian legal obligations

Mandatory to report incidents to FAMHP:
(Royal Decree 1999 on MD article 11)

- ..
- Healthcare professionals (HCP)
- Contact point of materiovigilance (CPM)
  Mandatory for every hospital (often head of pharmacy)
- ...

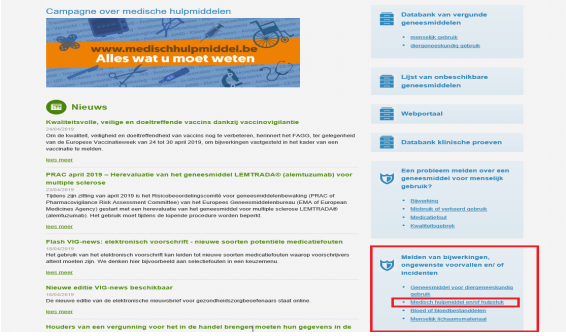
FAMHP website:

- Incident report form for non-manufacturers
  Filled out form => meddev@fagg.be | meddev@afmps.be
- Manual on how to report incidents

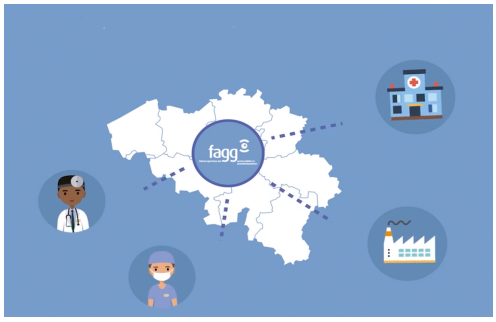
FAMHP Incident form

5. Informatie over het medisch hulpmiddel	
Beschrijving van het hulpmiddel (bv. pacemaker, infusieset, heupimplantaat ...)	
Commerciële naam	
Catalogusnummer	Modelnummer
Serienummer (schrijf n.v.t. wanneer niet beschikbaar)	Lotnummer (schrijf n.v.t. wanneer niet beschikbaar)
Versienummer van de software	
6. Informatie over het incident	
Datum van het incident	Implantatieduur (wanneer van toepassing)
Beschrijving van het incident (zo gedetailleerd mogelijk)	

FAGG: Homepage – notifying incident



The role of competent authority ?



The competent authority: Risk analysis

- Risk assessment of incidents, FSCAs and other vigilance data (including adequacy of manufacturer's actions)

The competent authority: Monitoring

- Monitoring manufacturer's follow-up actions
- Assessment of vigilance procedures
- Search for trends, signals, etc. in the data

The competent authority: Collaboration

- Collaborating with other European and international authorities, notified bodies, scientific and clinical community, patient organisations, etc.

The competent authority: Scientific literature

Follow-up on scientific literature to find new emerging risks, new failure modes/side-effects, changes in risk-benefit ratio, state-of-the-art, etc.

"Good news.
Your cholesterol has stayed the same,
but the research findings have changed."

FAMHP website on materiovigilance

Campaign: medical devices & materiovigilance
www.medischhulpmiddel.be
www.dispositifmedical.be

FAMHP website - materiovigilance
https://www.fagg.be/nl/MENSELIJK_gebruik/gezondheidsproducten/medische_hulpmiddelen_hulpstukken/materiovigilantie
https://www.afmps.be/fr/humain/produits_de_sante/dispositifs_medicaux/materiovigilance

Additional information

FAMHP website - medical devices
https://www.fagg.be/nl/MENSELIJK_gebruik/gezondheidsproducten/medische_hulpmiddelen_hulpstukken
https://www.afmps.be/fr/humain/produits_de_sante/dispositifs_medicaux

European Commission – medical devices
https://ec.europa.eu/growth/sectors/medical-devices_en

Contact

Federal Agency for Medicines and Health Products - FAMHP

Place Victor Horta 40/40
1060 BRUXELLES

tel. + 32 2 528 40 00
fax + 32 2 528 40 01
e-mail meddev@fagg-afmps.be

www.fagg.be - www.afmps.be

Follow the FAMHP on Facebook, Twitter and LinkedIn

Your medicines and health products, our concern

famhp .be