Safety notices and vigilance
A regulator's perspective

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Purpose of post-market surveillance, vigilance & safety notices

- Continuously verify/monitor the benefit/risk profile of medical devices in the real world compared to pre-market phase
- Take the appropriate measures to reduce/eliminate the risks and the harms of medical devices in the market
- Inform the (end-)users of the medical devices affected, the risks associated and the measures they can take to lower the risk + action the manufacturer will take

➢ **Increased safety of all medical devices in the market**
➢ **Increased patient safety and public health**

European context

New regulation + incorporation of IMDRF work

EUDAMED: European database on medical devices (manufacturers, devices, vigilance, pre-market data, market surveillance,…)

- ➢ including UDI database

- 1 vigilance database, instead of 31 separated vigilance databases

	Population	Incidents/year	Safety Notices/year
BELGIUM	11.5 million	4,500	600
EEA+TR+XI	+500 million	+100,000	~2,000

- Inclusion of IMDRF adverse event terminology to all vigilance reports
- Signal detection foreseen on vigilance data
- Transparency to the public (devices, vigilance data, safety notices,…)

Opportunities

Triumvirate of UDI, IMDRF adverse event terminology and device nomenclature (GMDN/EMDN/…)

- Deeper understanding of vigilance data within a jurisdiction

- Allows to incorporate other data sources in a more straightforward way:
  - Device registries
  - Implant registries
  - Other data sources (e.g. reimbursement data)

- Easier way of combining data from other jurisdictions (using one or multiple coding systems)

➢ **Truly play our role as regulators and give meaningful insights to manufacturers, healthcare professionals and patients**

Challenges/opportunities

- Standardization/covergence of data fields/requirements
- Collaboration/sharing of experiences on signal detection in medical devices
- Increased patient self-care/self-monitoring/self-diagnostic
- Medical APPs, software, personalised medical devices
- Vigilance data is limited/biased
- The flow POST-market => PRE-market

Contact

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