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A competent authority perspective on IVD vigilance.

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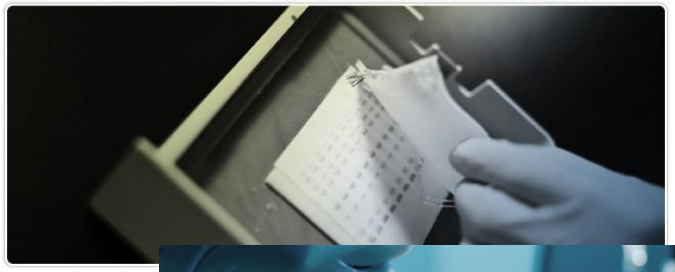
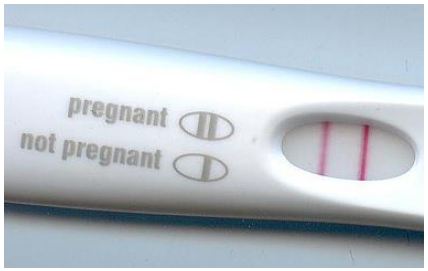
Overview of points covered

- Current legislation
- Changes to the vigilance framework
- IVD case file examples on EU vigilance cooperation
- Some future vigilance aspects

- Current legislation: IVD Directive 98/79/EC (KB 14/11/2001)
- Guidance: on vigilance MEDDEV 2.12-1 rev 8





Current legislation
Definition incident

- Incident (< IVD Directive 98/79/EC)

  a) any **malfunction**, **failure** or **deterioration** in the characteristics and/or performance of a device, as well as any inadequacy in the labeling or in the instructions for use which ***directly or indirectly*** might lead or might have led to the **death** of a patient, or user or of other persons or to a **serious deterioration** in their state of health,

  b) any technical or medical reason in relation to the characteristics or performance of a device for the reasons referred to in subparagraph (a), leading to systematic **recall** of devices of the same type by the manufacturer.

Current guidance
Definition reportable incident

- Reportable incident (<MEDDEV Vigilance 2.12-1)

1) An event has occurred

2) A **device** is associated with the event

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

Indirect harm as a consequence of an medical decision, action taken/not taken on the basis of information provided by the device *e.g.* incorrect IVD test result.

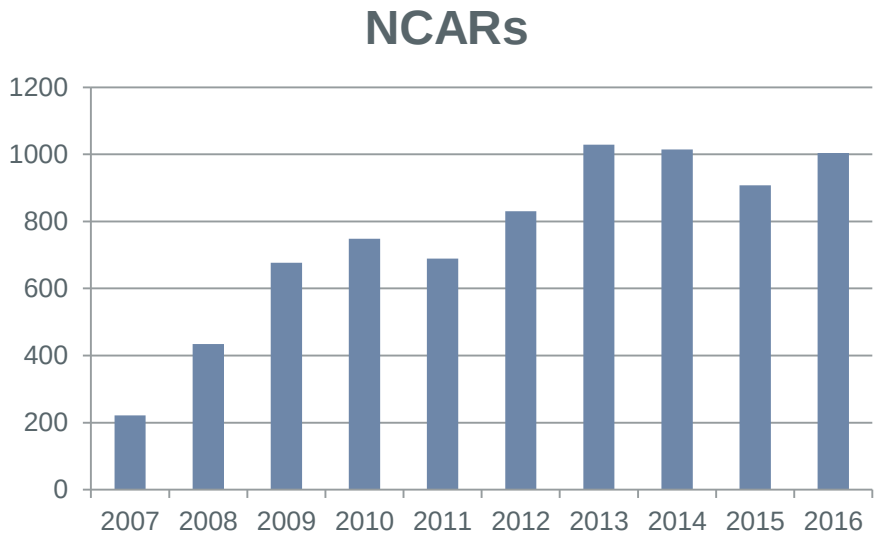
Current framework
Cooperation between EU competent authorities

- The Joint Plan for Immediate Actions (2012)
  - designed for MDs, but impact on IVDs
  - EU Commission
  - competent authorities (CAs)
  - notified bodies

Current framework
Cooperation between EU competent authorities

- Market surveillance
  - COEN (Compliance and Enforcement group)

- Vigilance
  - NCAR (national CA report)
  - Monthly vigilance TCs (>150 cases)
  - MDEG Vigilance



Current framework
Recent (proposed) changes (1)

- **MEDDEV Vigilance Revision 9**
  - **Device Specific Vigilance Guidance**: cardiac ablation & coronary stents, + others in development…

Report as individual incidents (in line with MEDDEV timescales)	Can be included in periodic summary reports (PSR)**		Report at the time the adverse trend is identified
Clinical / Symptomatic	Clinical / Symptomatic	Periodicity	• All reportable adverse incidents***

Current framework
Recent (proposed) changes (2)

- **MEDDEV Vigilance Revision 9**

  -improving **coordination between Competent Authorities**

  ↓

  -TF: IE (Chair), BE, DE, FR, UK

  -Aim (1): When is coordination between CAs necessary?

  -Aim (2): Explore how this can be better reflected in the MEDDEV.

Current framework
Recent (proposed) changes (2)

- **Coordination between CAs: when?**
  - concern regarding a particular incident or cluster of incidents
  - appropriateness of a FSCA is questioned
  - broader opinion on a vigilance issue is required
  - CA requires the assistance of the CA where the manufacturer, AR or NB is located
  - merit in setting up a taskforce to examine and coordinate a specific issue.

- **Coordination between CAs: mechanisms**
  - In many instances: vigilance enquiry form, email exchange or discussion at the monthly vigilance teleconference.
  - Some more involved and more complex issues: specific taskforce.

Current framework
Recent (proposed) changes (2)

- **Coordination between CAs: vigilance taskforce**

  - Composition of a taskforce: CA with the original concern, other CAs who support the concern, CA where the manufacturer or AR and NB are located.

  - Role: replaces the role of the coordinating CA that is outlined in the current MEDDEV.

  - More than 10 TFs already been formed during monthly vigilance teleconferences.

Current framework
Recent (proposed) changes (3)

- **MEDDEV Vigilance Revision 9**

  -**trend reports** and **manufacturer incident report (MIR)**

  -TF: UK (chair), BE, DE, ES, FR, IT, COCIR, MedTech Europe

  -Aim: address ongoing problems and misunderstandings over the expected and proper use of the Trend report form.

  -Solutions: an enhanced MIR with incident data compared to device market and provided in defined time periods, revised/new fields. Trend report for other events and non-reportable incidents.

  -Pilot phase ended and analysed.

  -new **MIR form** being developed.

Current framework
Recent (proposed) changes (4, 5)

- **MEDDEV Vigilance Revision 9**
  - -Field Safety Notice
    - -pilot phase ended
    - -new form being developed.
  - -Periodic Summary Reporting
    - -essential core information being defined.

Case file example IVD (1)
Blood glucose meters

- Problem with software for glucose values > 1024 mg/dL

- List blood glucose meters present on the European market and provide a statement that you have verified all these devices.
- Confirm that devices correctly process, display and store glucose concentrations of 1024 mg/dL and above.
- Feedback on the verification actions performed and copies of the test results.
- Results: 141 devices checked in 17 MS, 7 affected.

Case file example IVD (2)
Interference reactions

- Interference of certain drugs with Trinder-based reactions
  -> could lead to falsely low results.

- Interference of anticancer drug fulvestrant with estradiol immunoassays
  -> could lead to falsely high results

=> List, confirmation and feedback on the verification actions

Future IVD legislation
Classification

- Classification of IVDs:
  - A, B, C & D: risk based (low -> high)
  - Conformity assessment according to class

	Individual Risk		Public Health Risk
Class D	High	and	High
Class C	High	and/or	Moderate
Class B	Moderate	and/or	Low
Class A	Low	and	Low

Future IVD legislation
Vigilance

- Definitions:

Incident

any **malfunction** or **deterioration** in the characteristics or performance of a device made available on the market, including use-error due to ergonomic features, as well as any inadequacy in the information supplied by the manufacturer and any **harm** as a consequence of a medical decision, action taken or not taken on the basis of information or result(s) provided by the device;

Serious incident

any incident that **directly or indirectly** led, might have led or might lead to any of the following:

- the death of a patient, user or other person,
- the temporary or permanent serious deterioration of a patient's, user's or other person's state of health,
- a serious public health threat.

Future IVD legislation
Vigilance

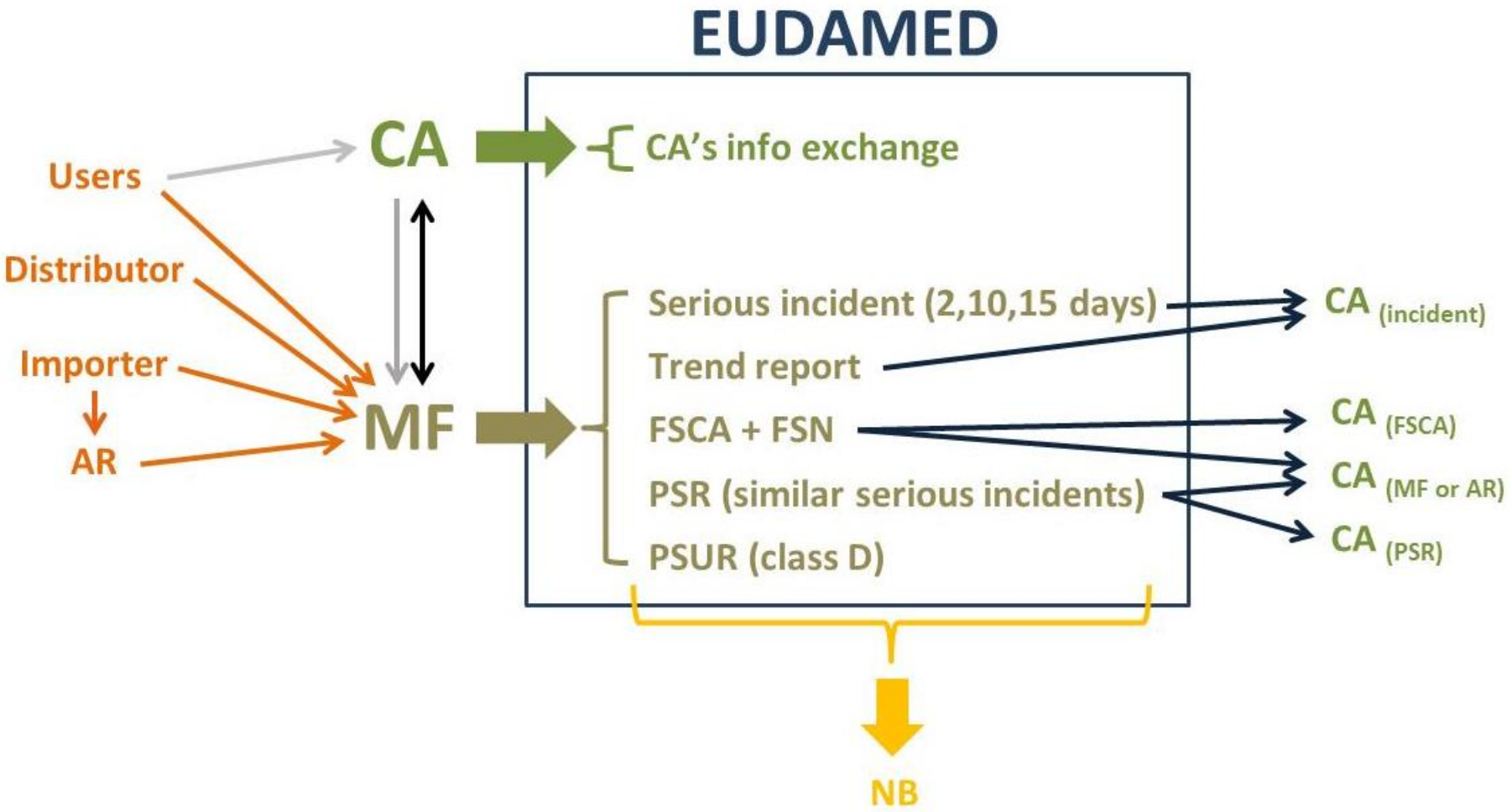
- What to report?

  - Serious incidents (except expected erroneous results which are clearly documented and quantified in the product information and in the technical documentation and are subject to trend reporting).

  - FSCA

- Method of reporting: electronically
- Periodic Summary Reporting for similar serious incidents
- Trend reporting of incidents (not serious)
- Coordination between CAs

Future IVD legislation
Vigilance



Future IVD legislation
Periodic safety update report (PSUR)

- class C&D

-> the conclusions of the benefit-risk determination

-> the main findings of the PMPF; and

-> the volume of sales of the device and an estimate of the size and other characteristics of the population using the device and, where practicable, the usage frequency of the device.

- Update annually
- Report in Eudamed for class D
- Notified body involvement

Future IVD legislation
Periodic safety update report (PSUR)

- Development of the PSUR form
- Substantial guidance document needed to support completion of the form
- EMA Guideline on good pharmacovigilance practices (GVP) Module VII – Periodic safety update report proposed as good starting point
- Add section on logistics of provision of the PSUR:

  how to submit, whom to submit to, how to define scope of the PSUR, periodicity.


Hey, where does the computer send our incident reports to?
YOU KNOW, I'VE NEVER CHECKED.
NICE
NAUGHTY

Thank you!