Quality of customer information concerning product problems of medical devices with main focus to in-vitro diagnostics as published by BfArM 2005 - 2012

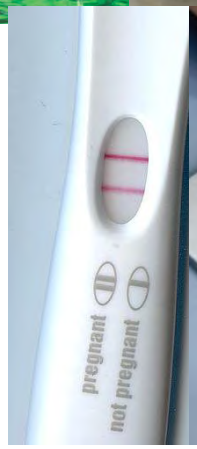
J. Hannig
Pharmaceutical Institute University Bonn

PhD Presentation
1.2.2014

universitätbonn

Drug Regulatory Affairs

Examples of IVD



Risks caused by IVD

Examples of direct harm: mostly users

- Risks caused by harmful biological substances (e. g. infection) or chemical compounds (e. g. chemical burns) in cases of usage, storage and disposal
- Risks caused by mechanical injury (e. g. needles) or electricity

Examples of indirect harm: mostly patients

- Erroneous results followed by medical consequences (delay of therapy)
- Incorrect medical or therapeutic diagnoses (false medicamentation)
- Additional or false diagnostic or therapeutic measures

=> reportable incidence: Direct harm of a patient
Observed or expected fault of a medical device.

=> Report to Competent Authority

What to do in case of a reportable incidence?

The competent authority (CA) must be informed about the product failure:

- Customer: Information of manufacturer and CA
- Manufacturer: Information of CA

  Field Safety Corrective Action (FSCA)

  Information of customers via

  Field Safety Notice (FSN)

- CA: Information of other CA`s via Competent Authority report

  Information of customers via FSN on homepage

  Evaluation and surveillance of FSCA

  Scientific analysis of notifications

Federal Institute for Drugs and Medical Devices (BfArM)

Guideline MEDDEV 2.12-1 rev 8

The MANUFACTURER should use a distribution means ensuring the appropriate organisations have been informed, e.g. by confirmation of receipt.

The FIELD SAFETY NOTICE should be on a company letterhead, be written in the language(s) accepted by the National Competent Authority(s) and include the following:

1. A clear title, with "Urgent FIELD SAFETY NOTICE" followed by the commercial name of the affected product, an FSCA-identifier (e.g. date) and the type of action.
2. Specific details to enable the affected product to be easily identified e.g. type of device, model name and number, batch/lot or serial numbers of affected devices and part or order number.
3. A factual statement explaining the reasons for the FSCA, including description of the device deficiency or malfunction, clarification of the potential hazard associated with the continued use of the device and the associated risk to the patient, USER or other person and any possible risks to patients associated with previous use of affected devices.

Guideline MEDDEV 2.12-1 rev 8

4. Advice on actions to be taken by the USER. Include as appropriate:

    # identifying and quarantining the device

    # method of recovery, disposal or modification of device

    # recommended review of patients previous results or patient follow up, e.g implants, IVD

    # timelines.

5. A request to pass the FIELD SAFETY NOTICE to all those who need to be aware of it within the organisation and to maintain awareness over an appropriate defined period.

6. If relevant, a request for the details of any affected devices that have been transferred to other organisations, to be given to the MANUFACTURER and for a copy of the FIELD SAFETY NOTICE to be passed on to the organisation to which the device has been transferred.

7. If relevant, a request that the recipient of the FIELD SAFETY NOTICE alerts other organisa-tions to whichincorrect test results from the use of the devices have been sent. For example failure of diagnostic tests.

8. Confirmation that the relevant National Competent Authorities have been advised of the FSCA.

9. Any comments and descriptions that attempt to a) serve to play down the level of risk in an inappropriate manner and b) advertise products or services should be omitted.

10. Contact point for customers how and when to reach the designated person. An acknowledge-ment form for the receiver might also be included (especially useful for MANUFACTURER's control purposes).

Aim of this Thesis

Analysis of FSCA and FSN regarding

product problems of medical devices with main focus to in-vitro diagnostics as published on the BfArM-Homepage in respect to the MEDDEV-Guideline:

- Number of notifications sent to BfArM 2005 – 2012
- related to IVD: 3452
- Number of FSCA published by the BfArM
- 2005 – 2012 related to IVD: 1257
- Ratio IVD-FSCA / IVD-notifications: 36.4 %

Materials and methods

Included are all reports received by the BfArM between January 2005 (start of publication of FSCA on BfArM homepage) and December 2012

Analysis of cases related to tests, reagents calibrators and control materials for diagnostics

Analysis of German and English FSN according to the Guideline MEDDEV 2.12-1 rev 8

Incomplete example of a Field Safety Notice

Microtrol™ Campylobacter jejuni - Kat. Nr. 254645

Sehr geehrte

wir wurden von unserer Qualitätskontroll-Abteilung informiert, dass eine Charge des o.g. Kontrollstammes verminderte Wachstumsfähigkeit aufweist. Unseren Unterlagen entnehmen wir, dass Sie mit der betroffenen Charge **Nr. 820021** beliefert wurden.

Bitte verwerfen Sie alle Restbestände dieser Charge, wir werden Ihnen in Kürze kostenlosen Ersatz zuschicken.

Um solch einen Vorfall in Zukunft zu vermeiden, haben wir die bisherigen Lagerbedingungen (-20 bis +4°C) auf **-30 bis -15°C** (Gefrierschrank) abgeändert.

Bitte entschuldigen Sie diese Unannehmlichkeiten.

Mit freundlichen Grüßen,

Becton Dickinson GmbH

[redacted]
Applikations-Spezialistin
BD Diagnostics – Diagnostic Systems

- No clear title with „UFSN“ and no type of action
- No FSCA identifier
- No information about review of previous results
- No information about risk with previous use of affected device.
- No request to pass the FSN to all who need to be aware of it within the organisation or to other organisation.
- Confirmation that the relevant National Competent Authorities have been advised of the FSCA.
- No contact data
- No acknowledgment form

Thank you for your attention