



HORIZONS

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**Vigilance and Postmarket Surveillance:
A Review of the European
Guideline MEDDEV 2/12, Rev 5**

Presented by:
Jaap Laufer MD, PharmD
Vice President, Regulatory & Public Affairs
Emergo Group, Inc.



The EU MEDDEV on Vigilance was updated in 2007

- MEDDEV 2-12.1 rev 5 replaces rev 4 issued in 2001
- Clarifies reporting requirements and enacts more stringent timeline requirements, inter-CA communication
- Defines content of the European database (EUDAMED) as an adverse event repository



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SOME KEY FEATURES of MEDDEV 2-12 Rev 5

- 78 pages - biggest MEDDEV to date
- Complicated, multi-interpretative compromise, closer to MDR & GHTF than Rev 4
- Strong disclaimers re: “legally compulsory”
- FIELD SAFETY CORRECTIVE ACTION (FSCA), FIELD SAFETY NOTICE (FSN), USE ERROR and ABNORMAL USE are new concepts introduced in this revision
- EUDAMED makes its introduction

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Overview of new items (I)

- ✓ User Error(4.20) “Act or omission of an act, that has a different result to that intended by the MANUFACTURER or expected by the OPERATOR of the MEDICAL DEVICE. “
- ✓ Abnormal Use (4.1):” a result of conduct which is beyond any means of risk control by the MANUFACTURER. “

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Overview of new items (II)

- ✓ Field Safety Corrective Action (4.6) includes Recall, Retrofit, etc.
- ✓ Field Safety Notice : Dear Doctor Letter, etc. (4.7)
- ✓ Immediately (4.9) “without any delay that could not be justified. “
- ✓ Indirect Harm (IVD) (4.11)

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Overview of new items (III)

- ✓ Periodic Summary Reporting (4.16)
- ✓ Serious Public Health Threat (4.17)
- ✓ Trend Reporting (4.18)
- ✓ Unanticipated (4.19) “A serious deterioration in state of health is considered UNANTICIPATED if the condition leading to the event was not considered in a risk analysis.”

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Event or Incident, both or none?

- The term “Near Incident” was deleted, “Events” and “Incidents” were introduced.
- All Incidents **are** Events, but **not all Events are Incidents!**
- Events may be malfunction, mislabeling or labeling deficiency, degradation, etc.
- Whether an “event” is an “incident”, must be determined quickly (5.1.1)

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When to Report (5.1.1)

- An event is reportable if
- a. it has occurred (*sic!*) AND
 - b. The manufacturer’s device is suspected to be a contributory cause of the Incident, AND
 - c. the event led, or might have led to the death or serious deterioration of health of patient, user or other person

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Reporting timeline differences between old MEDDEV and the Directive

- Rev 4 (*old*) required Incidents to be reported within 10 or 30 days
- National laws vary from 2, 5, 10, 15 and 30 days, or “as soon as possible” (France)
- All were somewhat incorrect since MDD states one needs to report “immediately.”
- MEDDEV 2.12 rev 5 harmonizes this

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New Timelines

- Under Rev 5, if an Event is an Incident, it should be reported “immediately”
- Supposedly one has time to investigate **IF** reporting is justified, however.....
- Not every event can be assessed for reportability. CAs will be watching, though!
- No more than 10 or 30 days to report an event; only 48 hours if it is a matter of “Public Concern”

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“NEW” POST-MARKET OBLIGATIONS FOR MANUFACTURERS

- Manufacturer. must keep AR, CA, NB & Distributor informed of Incidents & FSCAs (3.3.1)
- Where applicable, manufacturer must keep NB informed of post-production phase issues potentially impacting the Certification
- Specific obligations for discontinued or custom-made products

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EXEMPTIONS FROM REPORTING (I)

- All subject to agreement with NCA !
- Periodic Reporting (5.1.2)
- Common & well-documented incidents (5.1.2.2)
- Deficient device prior to its use (5.1.3.1)
- Event caused by patient conditions(5.1.3.2)
- Service-life or shelf-life exceeded (5.1.3.3)

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EXEMPTIONS FROM REPORTING (II)

- Protection against fault functioned correctly (5.1.3.4)
- Expected and foreseeable side effects (5.1.3.5)
- Negligible likelihood of occurrence of death or serious deterioration of state of health

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EXEMPTIONS FROM REPORTING (III)

- **IN SUMMARY: always report unless the event is already well-known to the NCA(s). Evidence has to be collected in case of doubt to support the decision not to report!**

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Medical Device Side Effects

- Old rules exempted “side effects” from reporting
- Some manufacturers created long list of “side effects” so they would not have to report anything
- Side effects now reportable under certain conditions (still not obvious, but closer to MDR) (5.1.3.5)

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USER ERROR

✓ User Error(4.20) “Act or omission of an act, that has a different result to that intended by the MANUFACTURER or expected by the OPERATOR of the MEDICAL DEVICE. “

- User error reporting is mandated, if it led to death or serious health deterioration

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Abnormal Use

- ✓ Abnormal Use (4.1):” a result of conduct which is beyond any means of risk control by the MANUFACTURER. “
- Abnormal use is not reportable under this MEDDEV

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ACCESS TO THE DEVICE AND ANALYSIS

- ❖ Not taken for granted by the MEDDEV
- ❖ If manufacturer wants to perform destructive analysis, NCA should be pre-notified! Wait for 10 days following submission of Initial Incident Report
- ❖ Procedure seems very cumbersome and in fact, may be counterproductive

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Field Safety Notices (FSN)

- Rev 5 “recommends” an FSN be submitted to the appropriate CA 48 hours prior to release to allow for comment
- Provides solution to sending it to only one country (wait and see....)
- Language(s)!
- Guideline spells out exact content of the FSN!

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Field Safety Corrective Action (FSCA)

- Recall Notice is now replaced by the Field Safety Corrective Action
- Section 5.1 offers details after release
- Covers the recall proper as well
- If recall is ordered **outside** the EU, but product **is** sold in EU, the FSCA should be sent to the NCA

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FSCA (5.4.4)

- In MEDDEV Rev. 5, synonymous with recall or withdrawal!
- Detailed notification process with defined list of recipients and contents

National Competent Authorities Responsibilities

- Detailed in section 6
- The NCA should perform Risk Evaluation to allow definition of corrective actions
- Monitoring of corrective actions (6.2.3)
- Coordination between NCAs (6.3)
- Dissemination of information between NCAs (6.3.5)

IMPACT ON QUALITY AND OTHER MANAGEMENT SYSTEMS (I)

Risk Management ISO 14971

- Pivotal for classification, (pre-)clinical evaluation plans, labeling, and reporting!
- Failure to consider significant risk likely to prompt measures by NCA
- Regular updates required
- Document second most in demand after labeling by NCA
- New favorite at QSIT audits

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IMPACT ON QUALITY AND OTHER MANAGEMENT SYSTEMS (II)

- SOP on Incident or MDR reporting to be revamped:
 - Fast review prior to decision to report
 - Be prepared for disproportional response, incl. from unaffected NCAs
 - Be very accurate, complete and consistent in your reporting!

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IMPACT ON QUALITY AND OTHER MANAGEMENT SYSTEMS (III)

- CAPA SOPs
 - Should reflect the increased need to collect all data ww instead of previous focus on US (and perhaps Europe...)
 - Updated complaint handling and vigilance procedures should reflect globalization of communications concerning non-compliant product

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IMPACT ON QUALITY AND OTHER MANAGEMENT SYSTEMS (IV)

- Labeling
 - Exhaustive listing of AE does not preempt reporting of incidents any more
 - Failure to use mandatory language likely to elicit strong NCA response
 - Use of language unfit for intended user greatly increases risk for FSN or FSCA
 - Translation SOP required by NBs

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- Canada
- Vancouver
+1 604 628 6094
- United States
- Austin
+1 512 327 9997



- Europe
- The Hague
+31 70 345 8570



- China
- Beijing
+86 10 8260 8228 x808



- Australia
- Sydney
+61 0 2 9006 1662

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