MEDIMARK® EUROPE NEWS **April 2013**

The 2013 Revision Of The EU Vigilance Guidelines For Medical Devices

Revision 8 of MEDDEV 2.12-1, the new European Medical Device Vigilance Guidelines, will replace the current version on July, 2013. It may lead you to update your vigilance procedure.

The main addition in this new guideline version concerns the *In Vitro* Fertilisation (IVF) and Assisted Reproduction Technologies (ART) products which are now explicitly included within the scope of the vigilance system. Additional notes are related to the "Indirect harm" concept.

More clarity on the reporting of incident and FSCA is provided for manufacturers of devices that are not intended to act directly on the individual. Where the manufacturer of an IVD, IVF/ART or diagnostic medical device such as software, identifies that an event has or could result in INDIRECT HARM and that led or might have led to death or serious deterioration in state of health, he should submit a Manufacturer's INCIDENT Report.

INDIRECT HARM may be caused by imprecise results, inadequate quality controls, inadequate calibration, reagent failures (e.g. contamination, transcription errors and reduced stability), false positive or false negative results, IVD software anomalies (e.g. incorrect correlation between patient sample and the obtained result).
Where there is a risk that the above mentioned failures would either lead to a patient management decision resulting in an imminent life-threatening situation to the individual being tested, or to the individual's offspring, or cause death or severe disability to the individual or fetus being tested, or to the individual's offspring, an incident report or a FSCA shall be notified to the concerned competent authorities.

Advice given by the manufacturer to the users in the Field Safety Notice (FSN) may include modification to the clinical management of patients, recall of patients or patient samples for retesting or the review of previous results /samples.

Other considerations.
Based on the above, most of the Medical Devices manufacturers are not affected by the new guidelines.
The Incident and Field Safety Corrective Action (FSCA) report forms remain unchanged however, it shall not be forgotten to replace the term "revision 7" by "revision 8".

We can deplore that there is no additional guidance concerning the reportability of events and FSCA to the National Competent Authorities (NCAs). It will help manufacturers and allow a consistent application of the guidelines by all EU NCAs. For example, when you report an incident where the patient is seriously injured due to a use error to BfArM (German NCA): You receive immediately a letter telling *" Mr. X, As you assessed the incident to be reportable according to the German*

Ordinance, you affirm that an incident occurred that has led or could have led to the death or serious deterioration in the state of health of a patient "due to a malfunction of the involved medical device" Currently you declare in the report that a malfunction of the involved medical device is not related as a root cause of the incident." And then BfArM requests you to review your vigilance procedure for the assessment of incidents because the Criteria "A" was not fulfilled (meaning the event was nor reportable).
If you do not report the same incident to ANSM (French NCA), you are exposed to penalties.

Regarding FSCA, the main criteria for reportability to the concerned competent authorities is your Health Hazard Evaluation. The fact that the vigilance guidance includes examples of FSCAs that the manufacturer should report means that on the contrary, if the likelihood of a serious deterioration in the state of health is remote, the FSCA is not reportable.
However, in order to avoid any misunderstanding and interpretation by your Notify Body or competent authorities, we suggest you that if you consider that a recall is not reportable (No health risk), it is preferable to replace the terms "FSCA" by "FCA"' (Field Corrective action) an "FSN" by "recall letter" because no link to the safety of the patient or user.

Revision 8 of the EU guidelines on a medical device vigilance system can be downloaded at : http://ec.europa.eu/health/medical-devices/files/meddev/2_12_1_ol_en.pdf

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