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New MEDDEV Guidelines on Postmarket Clinical Follow-Up Studies

In addition to MEDDEV 2.7.1 rev.3, "Clinical Evaluation: A Guide for Manufacturers and Notified Bodies," that was published in December 2009, a new document (MEDDEV 2.12-2 rev.2) has been published, which describes the sources of data/documentation used in clinical evaluations and the appraisal and analysis of clinical data for CE-marked commercial medical devices. Both documents provide guidance for implementing section 1.1.c of Annex X of the 2007 amended Medical Device Directive (MDD), which requires that clinical evaluations and their documentation must be actively updated with data obtained from postmarket surveillance (PMS).

The new MEDDEV 2.12-2 rev.2 emphasizes the increased need for postmarket clinical follow-up (PMCF) studies to be considered to address issues linked to residual risk in drafting the risk-based PMS plans. This document provides guidance on the circumstances in which a PMCF study is indicated, the general principles of PMCF studies, the use of study data (e.g., to update instructions for use), and the role of a notified body in assessing PMCF plans and the results obtained from the plans as part of a conformity assessment.

So during the next audit, a medical device company's notified body may decide on the basis of these MEDDEV guidelines that a clinical evaluation is overdue or needs updating. The company has to evaluate the existing data to determine if it is sufficient to support the safety and performance for a device's intended uses; if not, the company must acquire additional data through PMCF studies.

PMCF studies can follow several methodologies such as the extended follow-up of patients enrolled in premarket investigations, a new clinical investigation, a review of data derived from a medical device registry, or a review of relevant retrospective data from patients previously exposed to the device.

It is important to note that if a medical device company chooses to conduct a new clinical investigation, the provisions in section 2.3.5 of Annex X of MDD stating that "serious adverse events must be notified to all competent authorities of the countries in which the clinical investigation is being performed" does not apply. Incidents should be treated following the company's standard vigilance procedure for CE-marked medical devices, which means conducting a reportability assessment and, if reportable, notifying only the concerned competent authority.

In the same way, no authorization from competent authorities is required. However, the relevant provisions in Annex X of MDD along with related guidance and standards (e.g., EN ISO 14155:2011, "Clinical investigation of Medical Devices for Human Subjects") shall apply.

The new MEDDEV guidelines on postmarket clinical follow-up studies can be downloaded at http://ec.europa.eu/health/medical-devices/files/meddev/2_12_2_ol_en.pdf. Other guidelines published in 2012, such as the new guideline for authorized representatives (MEDDEV 2.5/10), can also be downloaded from the EC Europa website at http://ec.europa.eu/health/medical-devices/documents/guidelines/index_en.htm.

Written by René Clément on March 2012