CMCDec08-20120314

Central Management Committee
Statement on
"Improvement of Readability of Instructions for Use (IFU)"

PROTECTING PUBLIC HEALTH TOGETHER

The CMC, in its first meeting on 1st December 2010, has identified **improvement of the readability of instructions for use (IFU)** as one of the areas which needed increased attention to promote safety and usability of medical devices and should be included in the considerations for revision of the medical device legislation.

Subsequently this goal has been anchored in the Council conclusions on innovation in the medical device sector (2011/C 202/03) and the Commission was explicitly invited to take this point into account in the course of its future legislative work.

Furthermore MS have taken this aspect on board of their wish list for the revision of the medical device directives.

While the legislative process is under way, reasonable efforts however have to be made already now on the basis of current legislation. It must be assured, that patients and professionals may use the devices as intended by the manufacturer and any ambiguities with regard to the proper and safe use due to deficiencies in the readability of IFUs are avoided.

This concerns very basically appropriate font sizes of text, quality of translations and understandability of texts and graphics, especially when proper/safe use comprises subsequent steps or procedures or where devices are used with accessories or other devices or products. The needs and abilities of intended users have to be taken into account. Appropriate checks should be performed by the manufacturer on suitable samples of target users whether IFUs are really readable and assure proper and safe use of the device. PMS procedures have to be sensitive to any indications of bad readability via vigilance or other channels and to any necessary corrective measures. Special care has to be taken to enable users to properly identify changes to the previous version of the IFU on the basis of a risk assessment.

The CMC encourages Notified Bodies to have a close look on the readability of IFUs. NBs should have a closer look on the procedures assuring proper translations and checking readability of IFUs on appropriate samples of target users.

Audits of QM-systems, esp PMS requirements should be sensitive to procedures to detect any indications of bad readability via vigilance or other channels and to perform necessary corrective measures.

Date of Decision:14th of March 2012