MEDIMARK® EUROPE NEWS **February 2013**

EU Medical Device Regulation's Scrutiny Procedure Could Hinder CE Marking Process

As soon as the European Commission published the proposed new European medical device regulations on September 26, 2012, industry stakeholders raised concerns about some of its provisions. Pan-European industry association Eucomed, which has entered into an alliance with the European Diagnostic Manufacturers Association (EDMA) to form MedTech Europe, and British industry association ABHI have questioned aspects of the regulation, especially the need for the so-called scrutiny procedure. The organizations firmly believe that it will ultimately harm patients and have a negative impact on European governments and industry. MHRA, the UK competent authority, launched in November a consultation to gather views on how the proposed legislative changes will impact UK stakeholders. The MHRA recognizes that changes to the regulation of medical devices on a pan-European level are needed but does not view the scrutiny procedure as the best way to achieve this.

The scrutiny procedure (Article 44) allows for the Medical Device Coordination Group (MDCG; see articles 78 to 80) to select certain product files for additional review before the CE Certificate is issued by a Notified Body (NB). This procedure initially would be restricted to Class III devices but could be extended to specific categories or groups of devices that may not be in the highest risk category. The main criteria are:

- a device or an underlying technology that is a subject of public health concerns;
- device novelty;
- files submitted by regulators that have a history of significant discrepancies.

The mechanism for scrutiny of certain conformity assessments can be summarized as follows.

The NB shall notify the Commission of applications for conformity assessments for the aforementioned devices (applications to supplement or renew existing certificates are exempt from this requirement). The notification shall be accompanied by draft instructions for use and a draft summary of safety and clinical performance.
The Commission shall immediately transmit this notification to the MDCG. Within 28 days of receipt, the MDCG may request a summary of the preliminary conformity assessment from the NB prior to issuing a certificate.

The MDCG may submit comments related to the summary of the preliminary conformity assessment no more than 60 days after submission. Within that period and no more than 30 days after submission, the MDCG may request additional information. The 60-day countdown is suspended until the information has been received. Subsequent requests for additional information from the MDCG shall not suspend the countdown.

Following that, the NB shall convey to the Commission an explanation of how comments were taken into consideration--including reasons for not acting on the comments--and its final decision regarding the conformity assessment in question.

In summary, when the MDCG decides to review the preliminary conformity assessment for a device, the delay for obtaining CE certification will be a minimum of three months, but it could be much more.

The final wording of the regulation may be published in early 2014, prior to the European Parliament elections, entering into force 20 days after publication and coming into full effect three years later in 2017. An additional delay of 18 months shall be accorded to implementation of an electronic device registration system.

The proposal of the future Regulation of the European Parliament and of The Council on Medical Devices can be downloaded at :http://ec.europa.eu/health/medical-devices/files/revision_docs/proposal_2012_542_en.pdf

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