41st meeting of the
Competent Authorities for Medical Devices

Overview

The 41st Competent Authorities for Medical Devices (CAMD) plenary meeting was held in Tallinn, Estonia on 16 and 17 November 2017. The sessions and speakers provided interesting updates and originated an intense discussion on a number of topics. The session highlights have been summarised below.

Regulatory framework

Erik Hansson provided an update from the Commission, underlining its key implementation priorities, namely, the EU governance system, the implementation acts related to the notified body designation process, common specifications on Annex XVI products and on reprocessing, design and establishment of the new EUDAMED and UDI system, and clarification of certain transitional provisions.

Kadri Tõnnisson presented the medical devices data base in Estonia. This was followed by a detailed presentation by Erik on the new EUDAMED system, where an overview was provided on the legal basis, contents, deadlines, work done and planned for EUDAMED.

Governance and management

John Wilkinson reported on activities of the Executive Group since the last CAMD plenary meeting. John also highlighted that the election process will take place ahead of the next meeting in May 2018. CAMD agreed on the need to continue with the CAMD for another cycle and to elect a new Executive to support migration to the new landscape.

Bernhard Bichsel provided a summary of the feedback received from competent authorities regarding the future of CAMD in context of the establishment of the MDCG.

Transition and implementation overview

Matthias Neumann provided an update on the Transition Subgroup, who are working to achieve a common understanding of the transition provisions in the new Regulations. The initial results will be discussed at the first MDCG meeting at the end of November, and will later be published on the CAMD website.

Niall MacAleenan informed the group that the European Implementation Roadmap, which was published at the end of October, sets out activities, priorities and assignments to be executed by the network. The working groups are currently creating detailed plans to implement the priorities. Niall sought a mandate from the CAMD for the next phase of work, which was to monitor the implementation progress of the working groups and detect arising issues. This mandate was approved by the CAMD.

Notified body session

Ana Burgos and Rainer Edelhäuser provided an update on the activities of the Joint Assessment Coordination Group and the Notified Body Operations Group (NBOG) since the last CAMD meeting.

Ana and Rainer informed CAMD that the two groups have provided input to the implementing act on codes and corresponding types of devices. They also highlighted that the process for designation of notified bodies is on track and that training will continue for joint assessors. They confirmed that the 2016 work items have been delivered and that future work items from the CAMD roadmap will be planned for.

National plans

Bernhard Bichsel provided an update on the resources tool and explained how Switzerland have applied the model to determine an appropriate level of resource to implement the new legislation. Thomas Wejs Møller and Suzana Ostarevic also provided updates on their national application of the tool.

The resources tool has proven extremely useful for those who have used it, especially in supporting the challenge of communicating how the regulations will impact on national authorities.

An action arose for CEG to discuss a way to develop common principles for national authorities wishing to use fees to fund national activities.

Practical updates

There were a number of practical updates provided. This included communication videos produced by Denmark and Switzerland, the 'human factors and usability engineering' guidance that the UK have produced, an update on the IMDRF work programme, an update on progress made on the joint action for market surveillance, and how Germany have applied information techniques to vigilance reports and device groups.