54th meeting of the EU Competent Authorities for Medical Devices (CAMD)

On 14-15 March 2024, the Belgian Presidency of the Council of the European Union organised the 54th meeting of the EU Competent Authorities for Medical Devices (CAMD) in Ghent, Belgium. The following topics were covered: an overview of the state of play in Belgium regarding market surveillance, vigilance and inspection activities, an update on the projects and initiatives launched under previous presidencies, as well as the further implementation of the MDR/IVDR and the challenges involved.

During the first session, Hugues Malonne, CEO of the Federal Agency for Medicines and Health Products (FAMHP), highlighted the central role of CAs in assessing and overseeing medical devices. By providing the CAMD with a clearer mandate, adequate resources and enhanced autonomy, the CAMD network can empower CAs to enforce regulations more effectively and ensure the integrity of EU healthcare systems.

The CAMD recognises the importance of continuing to collaborate with stakeholders and other networks and to build a more structured partnership. It also emphasises the need for active participation of members to remain an influential network in the field of MDs and IVDs.

An update of the different JAMS 2.0 work packages by each leading CA showed the progress already made on each theme. Objectives and concrete actions for short and medium term were presented.

One of the main topics discussed during the CAMD was the possible shortage of devices and more specifically the reporting of supply interruptions. To tackle CA's limited view on the state of the market, the increasing signals from healthcare professionals and the potential burden of shortages on healthcare systems and continuity of care, a New Work Item Proposal on shortages was introduced. The main objective is to create a system to share shortages data between manufacturers, CAs and the European Commission.

CAMD underlines the importance of proactively addressing the emerging challenges posed by orphan, custom-made and in-house devices. One of the main challenges for CAs in the field of custom-made devices remains 'know your actors'. A second difficulty is the lack of experience and knowledge of the MDR by these manufacturers. There are several ways to address this problem at both national and European level, such as working on pre-inspection questions and creating in-depth guidances. Regarding orphan devices, CAMD acknowledges the urgent need to find tailored solutions to overcome multifactorial barriers. The Orphan Device Task Force (ODTF) is working on a specific guidance on clinical evaluation and the role of expert panels in the OD certification process is being further explored. The importance to have special regulatory pathways for ODs is confirmed by several hospitals. They face specific issues related to in-house orphan diagnostics, which could lead to the lack of critically important tests for rare diseases and discouraging innovation in the field, resulting in missed, delayed or inaccurate diagnoses.

In conclusion, the CAMD will continue to work together on the implementation of the MDR & IVDR to ensure equitable access to safe and efficient medical devices for all who need them.