55th meeting of the EU **C**ompetent **A**uthorities for **M**edical **D**evices **(CAMD)**

On November 27-28, 2024, the Hungarian Presidency of the Council of the European Union held the 55th meeting of the EU Competent Authorities for Medical Devices (CAMD) in Budapest, the Hungarian capital. The agenda of the meeting was the continuation of the work, done under the previous presidencies, as well as activities focused on the main priorities of the present and near future.

The opening session was chaired by Norbert Kovács and was opened by Dr. Rita Pálffyné Poór, the Pharmaceutical Deputy of the National Chief Medical Officer, who also confirmed the objective of the event:

"*The CAMD project was created to improve collaborative communication between medical device competent authorities. In recent years, we have faced many challenges in Europe. The Covid19 epidemic has brought us several difficulties in the field of medical technology industry and devices availability, we could feel that unexpected obstacles cause many difficulties in cooperation. The CAMD meeting is a good opportunity to build cooperation and open new communication channels.*"

The CAMD sessions focused primarily on the practical application of the MDR (Medical Device Regulation) and IVDR (In Vitro Diagnostic Medical Devices Regulation), as well as the role of CAMD. The focus of the meeting included discussion on key operational activities and a robust discussion on key regulatory developments.

Operational Activities

- Updates were shared during the meeting on the JAMS 2.0 project and outcomes from the Art 10a TF which confirm the CAMD's ability to take on operational topics in a collaborative manner. The organisation's terms of reference (ToR) and rules of procedure (RoP) are being revised to reflect its cooperative role within the MD/IVD sector.
- Discussions on the interplay between the AI Act and MDR/ IVDR highlighted their close relationship. The need to define the capabilities and competencies required and clarification of roles for MSA and Notifying Authorities were discussed.
- Adaptations in the design of clinical investigations and data required to fulfill the requirements under the current framework were discussed to enable access of these products on the EU market.

Key Regulatory Developments

- Competent Authorities had a focused discussion on the regulatory developments in the network, noting the importance of the EU Commission's Targeted Evaluation, MDCG initiatives to enable more effective application of the regulations in the short term, and the importance of the competent authority voice in driving key initiatives to improve the application of the EU Regulations with the support of Heads of Medical Device Agencies. The importance of close cooperation with all key actors involved in the implementation and application of the new regulations was emphasised at the meeting.

CAMD recognises the importance of close cooperation between authorities and with all key actors involved in application of the EU Regulations. The renewed political focus on the medtech sector was recognised as driving change and the significance of the targeted evaluation in framing the next phase of EU Regulatory Development was emphasised. There was strong support for a thorough methodological evaluation of any future legislative initiatives that might result from the Targeted Evaluation.