The 52nd meeting of the EU Competent Authorities for Medical Devices (CAMD)

The European Competent Authorities for Medical Devices (CAMD) met for its 52nd meeting in Uppsala, Sweden on the 1st – 2nd June 2023 under the Swedish Presidency of the Council of the European Union. The CAMD meeting in Sweden was dedicated to some of the major challenges we are facing in medium- and long term and where we as network of competent Authorities can improve the practical application of the regulatory system for medical devices.

The CAMD is a well-established umbrella group under which the national competent authorities work to enhance their level of collaborative work, communication, and surveillance of medical devices across EU. The topics for the CAMD plenary was a result of preparatory work being carried out throughout the present presidency, and to be continued under the next presidencies.

"The CAMD network is an important forum for competent authorities to raise awareness and discuss practical challenges resulting from the application of the regulatory framework. CAMD will continue to work and collaborate with key stakeholders to ensure the core objectives of the regulations are achieved" says Chair of CAMD executive group Helena Dzojic.

Some of the major topics discussed at the CAMD plenary meeting

- How the CAMD network best support and deliver on the implementation and practical application of the MDR and IVDR, e.g., to increase safety of patients and medical devices available in Europe and improving harmonisation, consistency, and predictability in its application.

- The MDR/IVDR provide for a broad set of requirements on medical technologies accessing the EU internal market. In addition, the sector is impacted by reform of other legislations such as the pharmaceutical legislation and horizontal legislations such as EHDS, AI and HTA. The interplay between horizontal and sectoral legislation and its impact on economic operators and competent authorities was raised with the view of ensuring a common understanding and awareness of practical implications.

- In light of the new regulatory framework for medical devices and *in vitro* diagnostics, the CAMD governance was discussed to further strengthen its operation in coordination, communication and cooperation within the European regulatory system.

In the short-term perspective, CAMD recognises it is of utmost importance that manufacturers as soon as possible adapt to the MDR and IVDR requirements, approach a notified body and submit complete and compliant applications. This needs to be carried out in due time to avoid risk for disruption in supply of medical devices for European patients and users.