53rd meeting of the EU Competent Authorities for Medical Devices (CAMD)

The Spanish Presidency of the Council of the European Union held the 53rd meeting of the EU Competent Authorities for Medical Devices (CAMD) on the 19-20 of September 2023, in Santiago de Compostela, Spain. The agenda for this meeting was a continuation of the work done under previous presidencies, together with activities focus on the main priorities at this moment and in the near future.

During the opening session Mª Jesus Lamas, Deputy Director of the Spanish Agency for Medicines and Medical Devices affirmed, *"As regulators, we bear an important responsibility in ensuring that all patients across the EU, regardless of where they live, have equitable access to high-quality, effective, and safe innovative medical devices when they need them. CAMD, as the network of European competent authorities on medical devices, is a key element for success on this mission. These meetings are the perfect fora to identify new priorities, for having discussions on more pressure topics and for sharing our knowledge and best practices as a benefit for all the competent authorities and therefore patients and users".*

Following this idea of the importance of CAMD activities, two main topics of discussion were:

- Redefine the role of the CAMD and its Executive Committee and their connections with other actors as MDCG, Commission and stakeholders. CAMD will also explore how to optimise the link with HMA and especially via HMA Core Group dedicated to MD/IVDs. This work begins through the assessment on the results of the survey done to all competent authorities, leading to an update of the Terms of Reference and Rules of Procedure.

- The practical application of the MDR and IVDR and the role of CAMD on this task, looking at the work done until now to fulfil the core objectives to establish a robust, transparent, predictable and sustainable regulatory framework for medical devices, which ensures a high level of safety and health whilst supporting innovation.

One aspect to highlight during this meeting in Santiago was the joint session between the Heads of Agencies of Medicines (HMA) and the CAMD, creating an opportunity of a face-to-face join session between both networks. More frequent common topics of interest concern both fields as clinical trials vs clinical investigations, scientific advice or experts panels. CAMD recognise the importance to find spaces to strengthen the communication between medicines and medical devices authorities to ensure patient safety.

A follow-up of the applications numbers for MDR/IVDR and certificates issued under those regulations was also presented during this session, in the continuity of the work began at CAMD and now under the MDCG umbrella. Those numbers showed not to be satisfying even 6 months after the regulation 2023/607 publication. Competent authorities remind manufacturers to make the best possible use of the extra time granted by the transitional periods adapting their quality systems and devices to the MDR and IVDR requirements and submit complete applications to the notified bodies. All actors should join forces to avoid shortages of medical devices and the subsequent risks for patients.

As a conclusion, CAMD acknowledge the importance of a close collaboration with all the key actors involved in the implementation and application of the new regulations.

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