Medical device competent authority statement on the status of the EU regulatory system

July 12th 2024

The EU regulatory system for medical devices outlined in the Medical Device Regulation (MDR) and *In-Vitro* Diagnostics Regulation (IVDR) represents an important evolution over the previous legislation, seeking to ensure appropriate levels of protection of public health are in place for European citizens, creating an environment to allow access and innovation of new technologies and affording a predictable, consistent and sustainable regulatory framework.

The Regulations were proposed to update, address gaps and better define the regulatory requirements, particularly in relation to notified bodies, post-market requirements and clinical data, with the backdrop of several high-profile safety issues relating to implanted medical devices.

The medical device competent authorities believe that these Regulations are essential to improve confidence and provide a solid basis for enhancing and protecting public health by ensuring safety while supporting development and access to new technologies in Europe.

It is clear however that there are challenges in applying the Regulations for all stakeholders and the competent authorities are strongly committed to work to resolve issues, develop and secure the regulatory system.

Progress and status

Since entry into force in 2017, significant work has been done by the EU Commission and competent authorities, notified bodies and many manufacturers to implement transition to the new Regulations. While there have been many achievements along the way, all parties have been significantly challenged in progressing the application of the regulations in practice and in putting in place the necessary resources, capability and infrastructure. It remains essential, that all parties involved, including notified bodies and manufacturers continue to increase efforts and work to transition to the new regulatory framework. The effective application of the Regulations is a responsibility shared by all for the functioning of the system as a whole. We must also recognise the significant investment that many entities have made, and the work already completed to transition.

Significant delays in progression and practical application of the new regulatory framework have been experienced; costs have increased for all parties, with little transparency or predictability; this, together with planning challenges and capacity shortfalls at various points in the system, has contributed to uncertainty and hesitation in transitioning. This has resulted in risk of disruption to supply, shortage or lack of availability of essential medical devices, beyond the inevitable discontinuation and retirement of some devices previously certified, for example, devices that may no longer be considered the state of the art.

This has impaired the transition of legacy medical devices to the new Regulations, delayed the introduction of important improvements relating to safety and transparency, and potentially diverted the introduction of new technologies that may benefit people across Europe. Ultimately these challenges and unforeseen consequences if left unaddressed may have a negative impact on both health and enterprise in Europe.

It is clear that the objectives of the Regulations have not yet been fully realised. The medical device competent authorities consider that the objectives set out in the Regulations remain essential and relevant today as do the important requirements therein. The authorities remain

committed to the establishment of a predictable, reliable, secure and efficient regulatory system in Europe based on the MDR and IVDR, to advance and protect the health of people across Europe.

To date, four legislative amendments have been made to extend the transition periods due to these delays. These amendments have been necessary to mitigate risk of disruption to healthcare in Europe, however the medical devices competent authorities clearly recognise and prioritise the need to further assess and address the underlying challenges that necessitated these contingency legislative measures.

The medical device competent authorities will remain focussed on protecting the availability of medical devices which are truly essential to EU health system and we must also ensure that costs and requirements arising from Regulation add value, are clear, consistent, proportionate and justifiable.

Careful evaluation and action to secure an effective regulatory system

The medical device competent authorities welcome and fully support the European Commission's targeted evaluation of the Regulations.

We are committed to urgently work together with the European Commission, and as necessary relevant stakeholders, to ensure that we can identify tangible solutions and actions to resolve underlying challenges, develop and improve the application of the EU regulatory system as envisaged by the MDR and IVDR.

In addition to this, the competent authorities recognise the need to plan actions to: develop and improve the functioning of the regulatory system in the short and medium term for all impacted stakeholders; manage consequences, such as availability of medical devices; ensure appropriate staffing to fulfil all essential tasks effectively and efficiently; progress development of infrastructure and systems (such as the use of the expert panels and the timely legal application of EUDAMED) and to address the impact of sectoral and cross-sectoral changes (such as horizontal legislation).

Specifically, the competent authorities have identified the need to prioritise and focus our resources for actions across four thematic pillars: access and availability; governance and coordination; innovation and safety. The authorities are working to identify tangible actions to take in the short and medium term and to consider all possibilities within the MDR and IVDR including associated implementing acts.

In tandem, the authorities aim to identify further aspects of the MDR and IVDR that in the longer term could be supplemented or further supported to make them clearer, up to date and more effective in practice. This work is intended to help remedy the challenges faced by all stakeholders and also be relevant to the Commission's targeted evaluation.

Securing an effective regulatory system

The regulatory requirements introduced by the MDR and IVDR remain important, relevant and necessary today to protect and enhance the health of European citizens and to foster the development and introduction of beneficial technologies to Europe.

Further system development should be carefully and methodologically evaluated through evidence-based decision making and assessment of the impact of the existing requirements or any proposed developments, and through strategic collaboration between key stakeholders, in particular national authorities, the EU Commission and other relevant

institutions. We must carefully examine the resources, capability and infrastructure required and arising from the regulatory requirements to achieve an effective, efficient, proportionate and value-driven regulatory system.

We recognise that there is urgency on the need for development and improvement of the regulatory system, but doing so reactively and without a thorough analysis and evaluation could lead to significant further disruption and impairment to progress towards an effective EU regulatory system. Taking a wrong turn at this point is not an option.

The medical device competent authorities call on the European Commission to clearly prioritise medical devices in their next mandate.

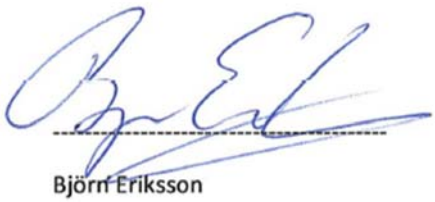
We stand ready to support and work with the Commission through the targeted evaluation and other initiatives to carefully assess and identify further measures to ensure that the regulatory system achieves its objectives, is applied efficiently in practice, affords appropriate public health and safety, serves the needs of its stakeholders, retains credibility and secures recognition and reliance on the regulatory system both within Europe and globally.

On behalf of the CAMD network

Thierry SIRDEY

Chair of the CAMD

On behalf of the HMA CG network



Björn Eriksson
Director General
Swedish Medical Product Agency