EDITORIAL

Time is of the essence for the "father of healthcare"

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Jesús Rueda Rodriguez heads the regulatory team of EDMA and ensures the association's active participation in the regulatory debates that affect IVDs in the EU. He is also involved in work at the international level, acting as the EDMA representative to the WHO and ISO, as well as a liaison to other associations on regulatory matters.

The proposal for an in vitro diagnostics (IVD) regulation currently under discussion in the European Parliament and Council of the European Union will chart the future of the regulatory system for IVDs in Europe.

Dubbed the "father of healthcare" by rapporteur of IVD Regulation Peter Liese, the various rounds of discussions are beginning to underscore the importance that IVDs have in healthcare as a pathway for guiding patient management decisions. And with this recognition, an important and more detailed look at the proposal is also starting to take place.

It's clear that IVD manufacturers will be controlled more strictly under the new regulations, and that notified bodies will also be more deeply involved. With the new classification system, they will have levels of oversight in about 90% of all IVD applications. However, the involvement of reference labs – which will provide a pool of scientific expertise to authorities and notified bodies, and test samples collected through unannounced visits – will mean dealing with new operators in the future.

Specific device types are currently being highlighted, and special care is being taken to ensure that they are safe and effective. This is the case for companion diagnostics, where there is a need to ensure that both IVD authorities and medicinal products authorities are satisfied that personalised medicine is delivering on the promise it holds. The same holds true for near-patient testing systems, which are growing in importance as a means for ensuring that testing results actually reach patients and have an impact in managing their health. Finally, it is important to underline that the specific requirements for IVD software will enable a better integration of the information that is transferred from IVDs to information systems.

The regulation takes a balanced approach between pre-market and post-market controls. In the pre-market setting, the use of Common Technical Specifications (CTS) for the highest risk IVDs continues to provide a very stringent requirement that has to be met before a diagnostic reaches the market. In addition, all IVDs will now have to be supported by clinical evidence. This is to include not just their analytical performance, but also clinical performance and scientific validity – in other words, knowing how the information that is generated by the IVD benefits the patient.

A lot of the questions that have been raised by the regulation will be addressed through the way in which it is implemented. In this, it is essential that implementation be driven by the need to ensure the safety and effectiveness of IVDs, while at the same time retaining relatively rapid access to the market for them. Only this combination will result in direct benefits to both the patients and the users of these devices.

Industry will have time to adapt, but that time must be used wisely. Collecting clinical evidence must begin as soon as the details are finalised. Those companies that begin an early programme of implementation will be in the best position to benefit from the advantages of the new system, which will include greater international convergence, as well as an increased confidence in a more stringent – but possibly still supple – system for regulating IVDs.