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EU IVD sector faces reg upheaval, while PMA threat looms

by Amanda Maxwell

The European IVD industry faces having to make big changes to comply with the anticipated new requirements of the forthcoming IVD Regulation, Jesús Rueda Rodríguez, regulatory affairs director at the European Diagnostics Manufacturers Association (EDMA), has warned in an interview with *Clinica*.

EDMA believes it is aware of the main topics of the review and is not expecting any surprises, he said, noting that the main points have already been discussed and covered by the press, and that the biggest changes will come in the well-publicised areas of classification and conformity assessment, and regarding clinical evidence.

However, the association remains vigilant with regard to suggestions that there should be a premarket approval (PMA) system for high-risk IVDs, as suggested by the European Parliament.

EDMA – like its counterparts at the European medtech industry association, Eucomed, with which it now shares the same chief executive, Serge Bernasconi – does not believe premarket authorisation is necessary in the medtech field, including for IVDs.

"In the case of IVDs, we already have a strong premarket system of Common Technical Specifications for the highest-risk IVDs, which works well and is as strict as it gets," Mr Rueda told *Clinica*.

One area that will impose more demands on the IVD industry is the anticipated Commission proposal for clinical evidence – essentially the first time this will be required for most IVDs.

The European Parliament is understood to be heavily supportive of this initiative. What is not yet clear, Mr Rueda pointed out, is how much clinical evidence will be needed and for which IVDs.

He added that clinical evidence requirements for IVDs need to be different from those that already apply to medical devices; the IVD sector is not looking at the direct clinical impact on the patient, as with medical devices in general, but rather at providing evidence of the way a product works to make the correct diagnosis, he explained.

There are also questions over how new post-market clinical follow-up (PMCF) requirements, which are now becoming far more important and hotly debated in the general devices field,

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