EDMA: EU IVD Directive revision should inspire confidence in companion Dx

New EU requirements are waiting in the wings for companion diagnostics and the IVD sector hopes that the measures will give body to this product group within the proposed revision of the IVD Directive and inspire greater confidence in this growing sector.

That is the view of Jesús Rueda Rodriguez, regulatory affairs director at the European Diagnostics Manufacturers Association (EDMA).

Although details have been scant so far, EDMA is confident that the revision will introduce new regulatory procedures for these products that will help drive this emerging market.

"Regulation of these products will become less ad hoc and more routine," Mr Rueda Rodriguez told *Clinica*. "There will be much more regulatory certainty and confidence, as a result."

So far, the vast majority of companion diagnostics are regulated under the lowest risk category under the IVD Directive. But the likelihood is that they will be seen as medium-risk devices and subject to third-party certification review by one of the EU's notified bodies. This should help reassure investors of the level of quality and safety in the product in a manner that has not normally been available before.

Indeed, the role and involvement of notified bodies, the EU's third-party certification bodies, will become much clearer, in his view.

It seems likely, Mr Rueda Rodriguez said, that the proposed EU definition for these products – "a device [or IVD] intended to select patients with a previously diagnosed condition or predisposition for eligibility of treatment with a specific medicinal product" – will remain.

The definition itself makes the link between the IVD and the pharmaceutical being used alongside it and highlights the need for regulatory procedures to be handled in a manner similar to combination products.

Moreover, specific rules will be introduced so that there are legal procedures for co-operation between the pharma regulators on the one side and notified bodies on the other for diagnostics designed as companions for specific pharmaceutical products.

In terms of how this might work, Mr Rueda Rodriguez drew a parallel with the way the notified body seeks the opinion of the pharmaceutical regulatory authority or European Medicines Agency (EMA) for the pharmaceutical element of a drug/device combination where the action of the pharmaceutical substance is ancillary to that of the device.

Mr Rueda Rodriguez is of the view that the consultation for companion diagnostics will work in a similar way, but effectively in reverse. For companion diagnostics, it would be the pharmaceutical regulatory body, or EMA, that would seek the view of the relevant notified body, he suggested.

In effect, this situation already exists in the medtech/pharma sector, he agreed, where the EMA consults with the notified body over the device element of combined ATMPs (combinations of advanced therapy medicinal products with medical devices).

But the situation is different with combined ATMPs, Mr Rodriguez said, because these are single products. Companion diagnostics used with medicinal products are two distinct products and there are the complexities of trying to develop a system that allow the two to reach the market at broadly the same time.

So while models exist that are useful when considering the future regulation of companion diagnostics for use with medicinal products, these will need modifying to work optimally and to engender the level of confidence that is needed in these matched products to give a new impetus to this potentially lucrative market.

Proposed new EU market surveillance guide out by year end

The EU Central Management Committee (CMC) has put forward a proposal for a new work item on market surveillance to ensure a continuous and equally high standard of supervision among member states.

This high-level group of national competent authority experts, which works to improve co-ordination of medical device regulatory compliance, aims to make available the final draft of a market surveillance guide before the end of 2012.

The CMC is proposing that the guide describes a logical sequence of surveillance measures, and indicates the steps that have to be taken from the initial triggering event to the final communication of actions taken.

The committee is also proposing that the guide be based on a common interpretation/definition of market surveillance in relation to medical devices currently available EU documents on market surveillance.

Great variation in responses

For its part, the European Commission's Compliance and Enforcement Group, COEN, also made up of competent authority experts, discovered when it carried out a "tour de table" of member state authorities that there was a high level of variation in the responses by member states to the questions of what the definition of market surveillance is in the EU and what are the key elements that comprise market surveillance .

These are pivotal questions, which are vital to the safety of EU citizens.

Action to tighten up and co-ordinate market surveillance is especially necessary following the demand by the EU Commissioner of the Directorate General for Health and Consumer Policy, John Dalli, for member states to reinforce their market surveillance following the lack of co-ordination among competent authorities to the PIP breast implant scandal late last year.

For full story, visit: www.clinica.co.uk, 30 July 2012