The European Commission’s overhaul of medical devices regulation

The European Commission published its long awaited proposal to overhaul the European regulatory system for medical devices in September 2012.

The proposed Regulation represents an ‘evolution’ of the existing regime – the more controversial proposals such as the introduction of a centralised marketing authorisation process were rejected.

The new rules seek to address the deficiencies of the current regime (outdated regulation, unequal protection, inconsistent implementation, lack of transparency) by building on the following key themes:

• A shift towards a ‘life cycle’ approach to regulation
• Increased safety and improved traceability of medical devices
• Greater coordination and harmonisation across the European Union (EU).

The new rules will affect everyone in the medical devices supply chain from manufacturers, Authorised Representatives (ARs), importers and distributors. They are expected to be adopted in 2014 and the new regime will likely come into effect by 2019.

A shift towards life cycle regulation
The proposed Regulation promotes a shift towards a ‘life cycle’ approach to regulation by codifying the European guidance (the MEDDEVs) into the Regulation, making them mandatory. This means that for devices in lower risk categories there is a greater emphasis on post market regulation and surveillance, whereas the focus for devices in higher risk categories is when they first declare compliance at the CE marking stage. This is a positive development and will bring the European system more in line with the approach of other regulatory bodies such as FDA (US) and the TGA (Australia).

There are also provisions that clarify the role and the responsibilities of competent authorities, Notified Bodies (NBs) and the various players in the supply chain in the field of vigilance and post market safety. In particular, NBs will be now increasingly taking on a ‘policing’ role and will be expected to carry out sample checks and unannounced audits after a product has been placed on the market.

Increased safety and traceability
The general safety and performance requirements largely resemble the Essential Requirements under the current regime. However, some new provisions have been included to take account of recent advances in technology (eg rules relating to devices that include biological materials, software in devices and standalone software). Devices will also need to have a "unique device identifier" (UDI) so that they can be traced back to their supplier. This aims to tackle the problems associated with Europe’s ‘borderless’ but nationally fragmented market.

There will also be a central European database for medical devices, which will be accessible to the public. The database will give patients and professionals more information on the medical devices that they might use or purchase. Devices will be classified into one of four different risk categories with updated health and safety and labelling requirements, and a new Medical Device Coordination Group will be set up to promote coordination between Member States, to address the current problem of national authorities dealing with similar problems in different ways.

Greater co-ordination and harmonisation
One of the weaknesses with the existing regime is that the current EU medical devices legislation have been implemented differently across Europe. The new rules therefore take the form of an EU regulation that would apply “as is” in all Member States. This is a welcome development and is expected to lead to greater harmonisation in the law.

The new rules also seek to improve the level of co-ordination and harmonisation at the administrative level. There will be uniform control of NBs, a centralised system for reporting adverse incidents and a more effective and efficient management of the regulatory system at the European level. The Commission has outlined a number of different ways that these objectives can be achieved, although the final decision will need to be taken at the political level.

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The European medical technology industry association Eucomed has responded to the proposals. Although Eucomed has welcomed many of the recommendations, it has focused on the areas of a systematic control procedure to improve patient safety, the need for clear scientific-based classifications of medical devices, and effective regulation of NBs as areas for development. The MHRA in the UK has also indicated its position within its consultation on the proposals, and has also highlighted the safety requirements for certain products and the new assessment procedure for NBs as key considerations. The MHRA has indicated its agreement with the single central registration and UDI system.

2013 and beyond

The proposed Regulations are a step in the right direction but questions remain on how some of the measures will be implemented at a practical level. The new UDI system and the various centralised processes will require significant investment in infrastructure and close cooperation between the various stakeholders. The change to a more coordinated regime will also undoubtedly bring its own challenges.

The Commission’s proposal will now be reviewed and debated by the European Parliament and EU Council. We will be following this process.

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