

## Regulatory Issues - a briefing paper

### **The Regulatory Regime**

Medical Devices are regulated under legislation which implements the EU Medical Devices Directives which were developed in the nineties under the New Approach. Generally the regime works well. A recent Commission review (2004) endorsed this view while making recommendations for certain improvements. These are now being implemented and an amending directive comes into force in March 2010.

However there is a body of opinion which believes that MD regulation needs to be more restrictive, often proposing medicines regulation as a model. Medical Devices are quite different from pharmaceuticals and need a regime which allows for the speedy introduction of innovative products. Any move towards a more prescriptive system would stifle innovation, damaging the interests of patients and industry. The EU Commission proposed a 'recast' of the MDD (May 2008). This proposal surprised everyone coming so soon after the review and met with considerable opposition including from industry. Intense lobbying during summer and autumn of 2008 resulted in the proposal being shelved to await the new Commission early in 2010.

The move of the Medical Device Unit to DG SANCO has resulted in some re-evaluation but the recast will undoubtedly be reintroduced during 2011 /12. However it is expected that some of the more unacceptable proposals, e.g. premarket approval for higher risk products, will have been dropped. Most of the proposed changes in the recast are perfectly reasonable and are supported by industry. However the risk remains that political pressure from some member states will have the effect of bringing these arguments back to the table and this must be resisted.

### **The Regulator (MHRA)**

In general the MHRA shares industry's view on the issues outlined above and has argued this position strongly in Europe. A paper has already been issued dealing in some detail with the other issues for the devices industry in relation to the Agency. It is essential that devices receive greater recognition and that a senior figure is appointed to champion devices not only within the agency but, more importantly, externally in the EU and in international forums such as the GHTF. It is also important that a succession plan is urgently developed for the senior device executives who are nearing retirement.

### **New Technologies**

Industry and the MHRA are working together to develop a new regulatory pathway for the introduction of products based on new and emerging technologies to ensure that such products reach the patient in a timely manner. This may need political support in due course.

## **Unique Device Identification (UDI)**

The recent report of the House of Commons Health Committee on Patient Safety highlighted the importance of Auto Identification and Data Capture (now more commonly known as UDI). There are global initiatives to introduce a standardised system of device identification in which industry, health authorities and providers are fully involved. It is likely that the EU will legislate (probably within the MDD recast) requiring all products to carry identifiers and this will be an enormous cost to industry and therefore eventually to healthcare over the next several years. Industry recognises the potential benefits of UDI, which go beyond patient safety, but these can only be realised if healthcare providers are engaged, motivated and correctly resourced to respond to the challenge. A good start has been made in the UK with the DH publication 'Coding for Success' but this needs to be followed through.

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