



Building a sustainable framework for medical devices regulation

Sir Kent Woods

The current medical devices regulatory framework in the EU is fundamentally sound

- Regulatory system highly regarded
- Rapid market entry compared to other systems

But...

- Medical technology rapidly advancing
- Divergence across EU countries
- Poor co-ordination & delayed decision-making

Recent media attention in the UK has questioned the rigour of device regulation



Dispatches

Under the Knife – May 2011



Surgery's Dirty Secrets – July 2011



Broad agreement exists around the principles that need to be addressed

- Notified Bodies
- Post-market surveillance
- Classification & borderline queries
- Transparency

Consistent across every issue identified is the need for greater central co-ordination

- Co-ordination does not mean centralisation
- Lessons can be learnt from medicines regulation – but fundamentally different regimes
- HMA & CMD(h) – substantial reduction in referrals to CMD(h) and CHMP
- Build on Central Management Committee (CMC) of Competent Authorities

The recast on its own will not be sufficient to remedy all of the issues identified

- Budgets across EU under pressure
- MHRA – 33% reduction over the next three years for devices work



- Resourcing key to system functioning effectively

A coherent approach to funding medical devices regulation across Europe is needed

- Charges vary between Member States
- Increasing divergence across Europe – confusing & onerous
- Opportunity to address this now
- Could bring benefits to both Member States & industry
- Invest to improve – e.g. pharmaceutical regulation in UK in late 1980's

Any fee regime would need to meet a number of criteria

- Support functioning of internal market
- Support innovation
- Light touch & minimal cost: <math><0.25\%</math> of total turnover across EU
- Transparent