US PMA no more of a safeguard than EU CE mark yet drawbacks significant, report finds
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The US FDA's premarket authorisation system for regulating high-risk medical devices not only delays patients' access to potentially life-saving technologies but does not safeguard them against risky products any more than the EU's CE marking process.

Moreover, it has a detrimental impact on small companies with limited resources which could cause these companies to stop operating, to the detriment of the development of innovative technologies in the US.

These are just some of the findings from a study conducted by Boston Consulting Group (BCG) and which has emerged less than a week before the EU Commission is expected to publish its draft medical device regulation texts - which is intended to amend the medical device directives - on 26 September,.

This is the latest in a series of reports which have been published against a backdrop of the EU and US challenging each other's different approaches to the regulation of medical devices.

The report, which is not publicly available but seen by *Clinica*, could be political dynamite; in June, the EU Parliament voted – albeit narrowly – for a switch to a PMA process for certain high-risk medical devices, while the medtech industry and most device regulators have been lobbying steadfastly against this (www.clinica.co.uk, 15 June 2012). Moreover, they have the support of EU Commissioner for Health and Consumer Policy, John Dalli.

The US has been highly defensive about its PMA system; this report is one of the latest shots questioning the US approach, and already the US FDA is promoting a series of initiatives that are intended to help encourage dialogue with industry and innovation.

Other recent reports have also emphasised that while the EU may offer a speedier regulatory route to market, its reimbursement hurdles – which often involve a further assessment of the product, ultimately result in longer time to market than in the US.

The BCG study assessed approval timing data from 172 devices that received PMA approval between 2000 through to 2011 and were also CE marked for the same indication approved in the US. It also carried out detailed device profiles of 89

products that received PMA between October 2007 and August 2011 (among these, 62 had CE marking information).

Looking at the 89 detailed device profiles, the study found there was "little difference in the rates of serious recalls under the EU and US regulatory systems".

"While some have suggested that European patients are 'guinea pigs' and subject to working out the kinks in new medical technologies, we found no evidence of this in our sample of 89 PMAs," according to the report. "Examining all original PMAs during this period with CE marking information, we found only two in which there were any recalls or safety issues in the period between European and US approval."

However, the average delay between medical devices being CE marked and receiving PMA was an average 43 months, or over three years, the study found.

The distribution of delay varied widely, with some devices not receiving PMA approval until six years or more after being CE marked.

This device lag has a significant impact on US patients, who miss out on potential health benefits that include reduced disability, improved quality of life, and greater patient choice, the report stated.

The report gave several case studies of medical technologies that had significant clinical benefits but experienced a considerable delay between EU and US approval.

These include, among others:

- Edwards Lifesciences' Sapien transcatheter heart valve, which provides a minimally invasive alternative to open heart surgery and could potentially benefit 75,000 patients who receive aortic valve replacements every year in the US. The device was CE marked in September 2007 but is still in the process of gaining approval in the US;
- Medtronic's Revo MRI SureScan pacemaker, designed to be MRI-compatible. The technology was approved in Europe 29 months before the US. Without access to this technology pacemaker patients cannot benefit from MRI scans, which are critical for early detection, diagnosis, and treatment of many diseases, according to the report; and
- Oxford Immunotec's T-SPOT.TB test, the first test that is an improved alternative to the traditional tuberculin skin test and allows for next-day test results without requiring a follow-up visit. The test faced a 49-month approval lag.

And it is not just the patients that are being impacted by the lengthy PMA process.

The study conducted some financial modelling to assess the impact of increased approval times on costs and product revenue for medical device companies.

"Our modelling suggest that the increased the impact of increasing FDA uncertainty and regulatory delays had significantly reduced the returns on medical technology

R&D and increased the uncertainty and cash needed to bring a new product to market."

While larger medical device companies might be able to offset this impact with revenue from other products in their portfolio, the small players who do not have a product portfolio would feel the hit.

Small device companies with limited resources suffer the most with approval delays, and many are unable to withstand the costs of long regulatory delays," the report suggested. And in the face of funding challenges, smaller firms may be forced to sell at low valuations or to discontinue development efforts, preventing life-saving innovations from ever reaching the market.

"The resulting decrease in innovation could jeopardise the competitive position of the US in the medical technology sector."

The report concluded by saying that it is not prescribing EU regulatory processes for the US nor suggesting that the EU process is perfect. The findings, however, point to the detrimental impact that the regulatory delays have on US patients and companies and that "more rapid approval times in the EU offer significant health benefits to European patients and to industry".

"Policy makers should be aware of the consequences of increasing FDA delays and elongating the EU-US device lag and of the potential negative impacts of reforms to the EU process that would elongate European review times," the report suggested.

"If approval requirements for complex medical devices are to be increased, they must be done so in a transparent and predictable fashion that does not further jeopardise the efficiency of the regulatory process and reduce future innovation."