Medical devices under scrutiny

May 18 2011, By Jonathan Wood

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So Dr Carl Heneghan, director of the Centre for Evidence-Based Medicine at the University of Oxford, begins a blog post on The Guardian site.

The term 'medical device' covers a huge range of products that have a medical use and are not medicines. The MHRA notes that this includes

anything from walking sticks and hip replacements to glucose monitors, blood pressure machines and pregnancy testing kits. Every day in the UK, millions of people safely use medical devices.

But it is the regulation of these devices that Carl and colleagues at Oxford are concerned with. They have just completed an analysis of product recalls in the UK as part of a joint investigation by the *BMJ* medical journal and Channel 4's documentary series Dispatches into medical device regulation. Carl's post explains the main findings:

"For the past 6 months, my group at the Centre for Evidence-Based Medicine at the University of Oxford has been looking at how many devices are recalled in the UK each year and what evidence supports their clinical use ... Device recalls are rising dramatically, from 62 in 2006 to 757 in 2010: a 1,220% increase. And yet, when we asked manufacturers for clinical data related to the recalls, we were stonewalled. Of 192 manufactures we contacted, only 53% (101/192) replied, and only four (2%) provided any clinical data."

In Europe, he writes, high-risk devices only have to establish safety and performance and do not have to prove they make a difference to patients. Carl contrasts this situation with that in the US, where approvals are undertaken by the FDA, and information held is readily available.

Carl calls for the current system of medical device regulation to be tightened so that it requires evidence of improvements in clinical outcomes for patients.

Carl is not alone in this opinion. The BMJ has published a series of commentaries from leading academics as part of its assessment of the issue, from Nick Freemantle, Stefan James, Alan Fraser, John Skinner, and C Di Mario.

The BMJ's press release says its investigation [see articles here and here] with Dispatches raises 'serious concerns about the regulation of medical devices and ask how well these high-risk devices are tested before they come onto the market.' It continues:

"[BMJ and Dispatches] explore a European approval process negotiated by private companies behind closed doors and reveal a worrying lack of public information about the number of devices being used and their potential risks. They also discuss links between surgeons paid to design devices and the companies promoting them. The investigations findings are clear. The current system is not fit for purpose and we urgently need better regulation to protect patients."

The Channel 4 Dispatches programme was broadcast last night at 8pm.

Separately, in an article in the *European Heart Journal*, heart specialists have called for an overhaul of the system for regulating medical devices such as heart valves and diagnostic imaging equipment, Andrew Jack notes in the Financial Times.

Jack's article in the FT also offers a comparison of the current approaches to medical device regulation in the US and in Europe:

*"[*The British Medical Journal has] published a series of articles highlighting weaknesses in the EU regulatory system for medical devices at a time of growing debate on reforms on both sides of the Atlantic ... European medical device trade bodies have also called for reforms to clarify existing regulatory standards and embraced with counterparts in North America, Australia and Japan through a Global Harmonization Task Force. However, they have also cautioned that excessive regulation risked damaging the medical device sector and could delay access to patients. They pointed to the US, where medical devices are introduced more slowly than in the EU as a result of tighter regulation, while, they

claimed, not improving safety."

Jack points to examples where UK regulators were the first to identify problems, and conversely where devices were rejected in the US but accepted then subsequently withdrawn or discontinued in the EU.

An MHRA spokesperson responded to the BMJ/Dispatches investigation, saying:

"Medical devices bring widespread health benefits for patients and the public but no product is risk-free. We ensure that the benefits always outweigh the risks. Our priority is to ensure that patients have acceptably safe medical devices*. We monitor all adverse incident reports and take prompt action to address any safety or performance concerns."*

The regulators note that manufacturers of all devices are required to have clinical data to support their performance claims for the device. In most cases, and in particular for higher risk devices, this information will come from a specific clinical trial on the device itself. However clinical data may also come from a literature review of the clinical information on equivalent devices. Where a manufacturer plans to carry out a clinical trial in the UK, agreement must be obtained from the MHRA.

The spokesperson adds: *"What must be borne in mind is the balancing act of generating clinical data pre-market and the benefit to patients of innovative products reaching the market place."*

Where this balance should lie is the question that concerns all of these parties.

Provided by Oxford University