

DEVICES: select the right approach

Though growing at over 5 per cent annually, the medical device industry is under pressure from strong competition and new regulations



There are an estimated 1.5 million different medical devices (MD) available worldwide and thousands of new and innovative ones are introduced to the market every year, demonstrating the importance of this expanding sector. The global system for the description and naming of medical devices includes 500,000 technologies divided into 10,000 generic groups.

The European classification system covering MD divides them by risk classes I, IIa, IIb and III, with class III covering the highest risk products. The higher the classification, the greater the level of assessment required to achieve a CE mark.

Competitive environment

Eucomed figures from May 2011 put European medical technology sales at €95bn, with €7.5bn reinvested in R&D annually (8 per cent of sales).

Medical technology accounts for about four per cent of the total healthcare expenditure in Europe, a figure that has remained more or less constant for a number of years.

That said, the European MD industry is growing at more than 5 per cent per year. The environment is very competitive, with each superseding improvement usually arriving within 18 to 24 months and pushing manufacturers to continue to innovate. This places the sector in the top tier of research investment in the EU, according to Eucomed. Furthermore, it supports 500,000 people, employed by 22,500 medical technology companies across the continent, 18,000 of these being small-to-medium or even micro-sized companies.

MD contribution

Since 1986, the population in Europe aged 65 years or more has increased 2 per cent and now represents over 17 per cent of the total population, which is the same proportion as in the US. This group continues to increase with better survival rates, for example:

- Mortality in heart attacks dropped 50 per cent
- Mortality rates in stroke decreased 4 per cent
- Mortality in breast cancer decreased 8 per cent.

MD technology has contributed significantly

to these success rates. It also contributed to a 13 per cent reduction in the average length of hospital stay between the years 2000 and 2008, which has, in turn, helped to cut healthcare costs dramatically.

To alleviate the increasing costs of healthcare in Europe overall, there is a need for shorter hospital stays and more effective treatments with better outcomes. However, the development of technology in Europe is still lagging behind the US and Japan in terms of overall investment in R&D and the patient's access to the outputs of this research, according to Eucomed.

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Total global healthcare expenditure was \$5.7tn in 2009, of which European healthcare expenditure accounted for \$1.78tn in 2009 (32 per cent) (see figure). The ‘big 5’ in Europe, namely Germany, France, Italy, UK and Spain, accounted for 22 per cent of the European total, which includes the existing 27 EU countries, plus Norway and Switzerland.

International standard

Different tests are required in the EU and US, including clinical investigations on human subjects, before a MD is granted marketing authorisation.

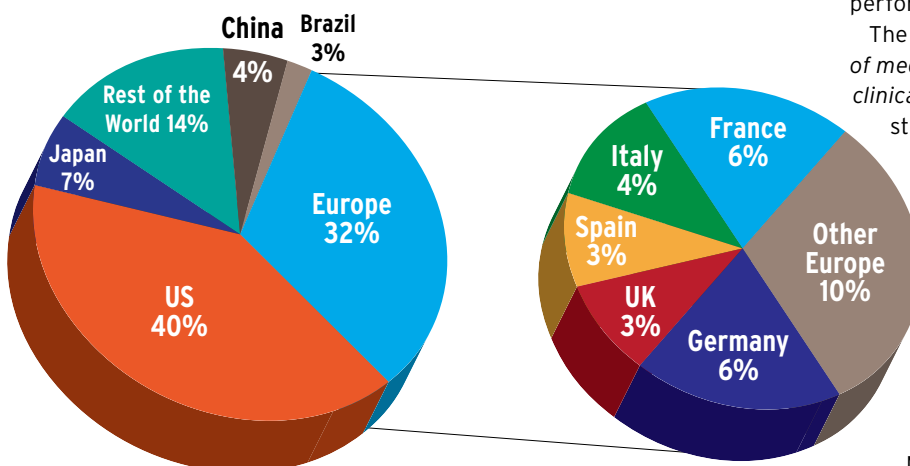
While European standards look for the proof of safety and performance of a device before granting the CE mark, the US requires proof of safety and efficacy.

This process can be costly if not carried out with the right methodology and constitutes a barrier to international trade if not performed at a globally acceptable level.

The new ISO 14155:2011, *Clinical investigation of medical devices for human subjects - Good clinical practice*, although primarily a European standard, sets out to be a global one that “will help to assess better the safety and performance of medical devices and so improve the protection of patients, provide a technical basis for regulation and minimise technical barriers to trade,” according to the International Organisation for Standardisation.

In the EU, the new standard will be adopted soon, with its publication in the *Official Journal of the European Union*. Meanwhile, the US Food and Drug

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Source: World Bank, EDMA, Espicom and Eucomed, 2009 calculations

➔ Administration (FDA) is reviewing it and will provide feedback in due course.

The fact that the term 'good clinical practice' is used in the title of the standard implies that its terminology and wording are closer to the GCP standard already used in pharma and accepted by the FDA for medical devices studies.

It should help to improve the quality of medical devices and encourage manufacturers to guarantee that their products do not compromise patient safety.

The standard replaces the earlier versions of the document, ISO 14155 - part 1 & 2:2003. The new ISO 14155:2011 aims to:

- Address good clinical practice for the design, conduct, recording and reporting of clinical investigations with medical devices
- Define general requirements for patient protection, ensuring the scientific conduct of the clinical investigation and the credibility of the results
- define the responsibilities of the sponsor and investigator
- assist sponsors, investigators, ethics committees, regulatory authorities and other bodies involved in the conformity assessment of MD. (Note: it does not apply to *in vitro* diagnostic devices.)

Companies should ensure that they are aware of how the new standard and its harmonisation in the EU will impact ongoing and planned projects. Otherwise, they risk their clinical investigations being rejected. This would, in turn, delay CE marking and could force companies to re-do administrative work or, worse still, a trial that was not set up according to the new rules.

Impact

Impacts of the new ISO standard:

- In general, the Competent Authorities (CA) could become more critical in their reviews of MD for approval
- For investigational products, the CA could consider that the sponsor is going too fast, and instead of performing one study to get the CE mark, should conduct two studies, namely a small pilot study and a larger study for the CE mark. This would also limit the initial exposure of a new device to a large population
- More post-marketing surveillance studies are required
- The potentially globally accepted ISO standard makes the mutual acknowledgement of study results easier.

Regulatory challenges

The EU's regulatory system was updated significantly in March 2010 and has proved to be highly successful, bringing the benefits of innovation to people more quickly. Now, people in the EU benefit from advances in medical technology five years earlier than in Japan and two years earlier than

in the US, on average, states Eucomed.

It should be said that the FDA has its own view regarding the time to reach market and comparison of the safety requirements in the different global regulatory systems, criticising the EU for the perception that MD are allowed on to the market with too little clinical substantiation.

However, on the issue of safety, measuring the number of recalls of medical devices shows that there is no difference between Europe and the US, as stated in a report by the Boston Consulting Group in January 2011.

MD Directives revision

The EC's MD Directives are over 20 years old and proposals to revise them by early 2012 have been put forward. Major topics for review include:

- Improving the device classification system, since the current system is inadequate
- Stricter requirements on clinical data from pre- and post-marketing studies to improve patients' safety, strengthen the fast track to market and ensure that manufacturers meet their obligations
- Notified bodies: Ensure that they have the expertise needed for analysing technical and clinical data and are supervised more strictly and consistently by the authorities
- European database on MD that improves information sharing, provides key information on MD, certificates, clinical investigations, safety issues and field corrective actions
- Further development of EU vigilance system, allowing coordinated analysis and EU-wide actions on safety issues
- Harmonising provisions on instructions for use and labelling.

The European Parliament has also consented to a common EU patent system to simplify the procedure for companies/innovators to register patents within Europe.

Although the business outlook remains positive, the pressure on the MD industry remains high, particularly for issuing new innovative products in ever shorter timeframes and in complying to increasing regulatory demands. These may overstretch the capabilities of small companies. In addition, with healthcare systems facing the financial impacts of a growing elderly population, price pressure remains high.

Only the fittest will survive the next decade.



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