At present, medical devices can be marketed across Europe only once they have been issued with a Conformité Européenne (CE) mark via the Medicines and Healthcare Products Regulatory Authority (MHRA) and its recognised Notified Bodies (of which there are five in the UK). In order for these bodies to function under the existing legislation, they must reside within the EU.

Given the UK’s departure from the EU, there is a growing concern that the UK’s medical device manufacturers will be unable to gain CE certification and trade their products competitively in the €100bn EU medical technology (Med Tech) market. This is despite the NHS being one of the largest buyers of medicines and medical devices in the world.

Leaving the EU will mean that UK manufacturers will lose their influence in regulatory, policy and legislative development. It is also not clear yet how the €8bn funding for medical technology from the European Research Council will be replaced. This funding is essential for innovation in the sector and is at the heart of the £17bn of business and 90,000 jobs here in the UK.

In short, extricating the UK from the EU without the Medical Technology industry suffering considerable damage, particularly for small businesses, will be a huge challenge.

As part of the UK’s wider post-Brexit industrial strategy, it is vital that Government and industry does something positive about this challenge. The Institution of Mechanical Engineers therefore recommends that:

1. The Government negotiates a Med Tech compliancy arrangement with the EU to ensure continuity in the CE marking process for UK manufacturers. This arrangement should be supported by parallel policies to encourage long-term investment in the sector. The goal is to attract Med Tech SMEs to the UK through clear support for innovation and product development.

2. UK industry and the NHS work together to ensure that they retain influence over future European regulation. This influence could flow from the purchasing power of the NHS, but should also be based on more formal post-Brexit arrangements negotiated by the UK Government on its behalf.

3. UK Research and Innovation must address the EU funding short-fall. This must take the opportunity to remove the current imbalance in support between early-stage start-ups and large established companies. A full commitment to implementing the Accelerated Access Review would go a long way to addressing this.
MEDICAL DEVICES & CE MARKING: THE IMPACT OF BREXIT

EU DIRECTIVES AND MED TECH POLICY

Medical devices are highly regulated and currently the UK legal framework that governs these devices originates from EU Directives that have taken EU Member States decades to achieve. The Medical Device Directive (MDD) 93/42/EEC, the Active Implantable Medical Devices Directive (AIMDD) 90/385/EEC and the In Vitro Diagnostic Directive (IVDD) 98/79/EC together regulate all manufactured medical equipment. However agreement has recently been reached on a new directive, which will replace the current MDD and AIMDD. The new directive will provide greater scrutiny of technical documentation and changes to the approval requirements for high-risk medical devices. It will also overhaul the classification system for in vitro devices (IVDs), bring stricter requirements on product safety and performance through clinical evaluation and post-market clinical follow-up, as well as improve methods of device traceability through the supply chain.

Ahead of the UK leaving the EU, it is imperative that the UK Government create a stable regulatory platform from which device manufacturers can implement any changes necessary to maintain their access to market.

UK MED TECH INDUSTRY

The medical device industry in the UK is a rapidly growing and diverse sector. The growth in personal health tracking, developments in artificial joints and organs, minimally invasive robotic surgery and aids for independent living, are all examples of some of the current activities in the £10bn UK Med Tech industry, which represents 12% of the European market.

The UK industry has been able to develop due to a strong research base, and a small yet dynamic set of innovative companies linked to NHS procurement. The turnover of UK Med Tech companies has been increasing recently by 50% per year, significantly ahead of the international trend, and now totals £17bn (8% of the global market). The sector comprises 3,000 companies employing approximately 90,000 people. About one third of these are employed in research & development and/or manufacturing. Most UK Med Tech companies are small businesses, three quarters having a turnover of £100,000 to £5m. Although all these businesses employ fewer than 250 people, and under 500 companies in the sector have a turnover of £100,000 to £5m. Most UK Med Tech companies are small businesses, three quarters having a turnover of £100,000 to £5m. A device that has achieved both FDA and CE mark regulatory clearance has access to over 75% of the global market. For a medical device manufacturer to affix a CE mark to its product, the company must demonstrate strict compliance with EU directives. The least risky devices (Class I) can be self-certified by a manufacturer that meets the medical quality standard ISO13485, but more risky products (Class II and III) have to be audited by a Notified Body via the Medicines and Healthcare Products Regulatory Authority (MHRA).

More than 4,500 medical devices were given CE marks across the UK in 2014, 500 of which were class III devices. While in theory the directives should ensure that CE-marked products are the same across the EU, the fact is regulations implementing and enforcing the directives are drafted individually by each Member State, which can interpret the directives slightly differently. Despite this, outside the EU and UK the MHRA can stand behind the CE or FDA approval, even though many also have their own regulatory processes.

Withdrawal from the EU without a new and respectful co-operation agreement with the MHRA could no longer reside in the UK and its Notified Bodies would not be entitled to conduct conformity assessments. Manufacturers would therefore not be allowed to fix the CE mark to their products. The UK could however, decide to adopt the EU Directives and recognise the CE mark as the domestic standard for certifying medical devices. In doing so UK manufacturers would have to appoint an authorised representative (similar to the MHRA) to act on their behalf.

Recent consolidation across the industry has left a relatively under-populated mid-size region between the very large companies and the small enterprises. International sales and marketing operations often require more people and many different, highly specialised, skills if they are to achieve reasonable sales growth.

For the UK to capitalise from a potentially more international market, it needs to rebalance support for medium-sized Med Tech companies to ensure successful pull through of new technology. This is because although initial research is best undertaken with small teams, high tech medical innovations, conversion into commercial product is often beyond their capabilities.

CE MARKING: FINDING THE RIGHT ROUTE TO MARKET

Internationally, there are two major schemes for approving medical devices for general sale:• The CE mark system within the EU• The FDA clearance system in the USA

A device has been achieved the FDA clearance system. However, many also have their total research funding) under the EU's (ERC) grants than any other EU country (16% of and academics with European Research Council (ERC) grants than any other EU country (16% of their total research funding) in the last 5 years. This is a substantial proportion of the R&D's total funding. More generally UK research centres and academic institutions attract more researchers and academics with European Research Council (ERC) grants than any other EU country (16% of their total research funding) in the last 5 years. This is a substantial proportion of the R&D's total funding.

Access to funding

About 6% of medical device annual sales and 10% of in-vitro diagnostic devices (IVD) annual sales are reinvested into research every year across Europe. For example, since 2010, the EU has contributed a total of €25m in research funding into treatment and cure research at Great Ormond Street Hospital and the Institute of Child Health (ICG). This is a substantial proportion of the ICG's total funding.

More generally UK research centres and academic institutions attract many researchers and academics with European Research Council (ERC) grants than any other EU country (16% of their total research funding) in the last 5 years. This is a substantial proportion of the R&D's total funding.

The UK could however, decide to adopt the EU directive, which will replace the current MDD and AIMDD. The new directive will provide greater scrutiny of technical documentation and changes to the approval requirements for high-risk medical devices. It will also overhaul the classification system for in vitro devices (IVDs), bring stricter requirements on product safety and performance through clinical evaluation and post-market clinical follow-up, as well as improve methods of device traceability through the supply chain.

RECOMMENDATIONS

The Institution of Mechanical Engineers recommends:

1. The Government negotiates a Med Tech complicity arrangement with the EU to ensure continuity in the CE marking process for UK manufacturers. This arrangement should be supported by parallel policies to encourage long-term investment in the sector.

2. UK industry and the NHS work together to ensure that they retain influence over future European regulation. This influence could flow from the purchasing power of the NHS, but should also be based on more formal post-Brexit arrangements negotiated by the UK Government on its behalf.

3. UK Research and Innovation must address the EU funding shortfall. This must take the opportunity to remove the current imbalance in support between early-stage start-ups and large established companies. A full commitment to implementing the Accelerated Access Review would go a long way to addressing this.

Despite this, the NHS continues to reduce its supply chain and streamline its procurement processes to comply with the Government’s requirements to save £22bn. Concern is therefore growing amongst these smaller suppliers that the NHS will turn to cheaper overseas alternatives rather than invest in UK-designed technology. This could inhibit low-volume, high-value and specialist technologies such as joint replacements and disease detection equipment. Without NHS support for smaller Med Tech suppliers, there is a risk that technology innovation, brought about by the existing symbiotic relationship, could be detrimental to patients and long term, fail to generate the NHS’s hoped-for savings.
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