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 should 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 the 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 regulates 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.1,2

Ahead of the leaving the EU, it is imperative that the UK Government creates 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 (6% 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 an annual turnover of over £5m.3-6

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 reharvest support for medium-sized Med Tech companies to encourage successful pull through of new technology. This is because although initial research is best undertaken with small teams, final 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 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 products, the company must demonstrate conformity 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, III and IV) 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 EU in 2014, 500 of which were class III or 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 manufacturers will be allowed to fix the CE mark to their products. Withdrawal from the EU without a new cooperation agreement would mean the MHRA would 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 assist with approvals to the UK approval process, so that they could be marketed back into the UK. A costly process with little benefit to the manufacturer.

Alternatively the UK Government could follow the example of Switzerland and agree to mutual recognition of medical devices based on a bilateral agreement with the EU. This could inhibit low-volume, high-value and specialist technologies such as joint replacements and disease detection equipment.7,8

ACCESS TO FUNDING

About 6–8% of medical device annual sales and 10% of in-vitro diagnostic devices (IVD) annual sales are reinvested into research every year across Europe.9 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 (ICCH). This is a substantial proportion of the ICCH’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 (6% of their total research funding)9. Under the EU’s last Framework Programme (2007 to 2013), the UK contributed 6% and yet won grants worth £8bn. Importantly UK domestic funding is very small in comparison, totalling about £400m through Innovate UK, EPSRC, Wellcome, Government Life Sciences.

Being outside the EU would not necessarily preclude the UK from taking part in European research programmes. Non-EU members do take part in EU research schemes, usually by paying for inclusion and accepting certain EU requirements, such as freedom of movement. However, UK researchers would lose the priority given to EU members, putting them at the back of the queue for ERC grants. Innovation funding and market access such as that identified in the Accelerated Access Review could go some way to compensating SMEs but it is inevitable that a “hard” exit from EU systems would severely affect both UK academia and small Med Tech companies.1,9

TECH ADOPTION IN THE NHS

Europe will see a doubling in the number of over-65s by 2060, and the number of older people living with diseases considered rare is expected to treble to over 4 million by 2040. One in three 10 to 11-year-old children is already overweight or obese; with 70% of children expected to be diagnosed with the condition by 2034. The Med Tech industry is set to play a fundamental part in addressing these issues. However, higher import costs on proprietary equipment post-Brexit, could result in an increase in the value of sales prices of UK-manufactured medical devices. The NHS is the largest purchaser of medical equipment in the UK and for most SMEs it is their sole customer.

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.7,8

RECOMMENDATIONS

The Institution of Mechanical Engineers recommends:

1. The Government negotiates a Med Tech compliance 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 should 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 challenge of funding the Med Tech sector. 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.
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