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TITLE PAGE

Title:

Relationship between EU Membership & UK medical device innovation

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ABSTRACT

a) 38 million people contact a medical device every day in the United Kingdom (UK).

The UK has over 3000 companies employing 76,000 people in medical technology.

Currently valued at £17 billion and growing at rates exceeding 6% the UK has remained a leader in medical device innovation. Governed under the European Union (EU) Medical Device legislations, it is demonstrated that this model, and the UK's continued membership accounts to an optimal balance between safety and risk with early access to new innovation. Leaving the European Union, would have a detrimental effect on UK businesses where EU legislation is used for market access. With the cost of regulation increasing, and the cost of products being forced to decrease, many UK businesses will no longer find it viable to innovate and manufacture within the UK.

Keywords

Medical device, European union, regulation, legislation

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Elements of this article were originally submitted to the UK House of Lords Science and Technology Select Committee on September 2015.

EU Landscape for medical device regulation.

Medical device manufacturers in the UK must comply with one or more of the following:

- Directive 93/42/EEC for medical devices,
- Directive 98/79/EC for *in vitro* medical devices (IVDs)
- Directive 90/385/EEC for active implantable medical devices (AIMD)

Currently the EU are updating these regulations, with publication expected in 2017/2018.

In addition, depending on the nature of the device, other EU legislation may apply – for example, electromechanical, cosmetic, pharmaceuticals and more. Furthermore, there are a number of European adopted standards which are used to demonstrate, or presume assumption of compliance to EU legislation. These are referred to as Harmonised Standards.

A harmonised standard is a European standard developed by a recognised European Standards Organisation: CEN, CENELEC, or ETSI. It is created following a request from the European Commission to one of these organisations. Manufacturers, other economic operators, or conformity assessment bodies can use harmonised standards to demonstrate that products, services, or processes comply with relevant EU legislation (European Commission, 2015). Such standards are published in the Official Journal of the European Union.

These three Directives (MDD, AIMD, IVD) form part of the 21 New Approach Directives which apply to products that can bear CE marking. CE marking is not a quality mark, but indicates to EU regulators that these devices meet all requirements of the appropriate Directive. CE marking is not used solely for medical device manufacturers, but applies to many other British industries. Regulation and patient safety are the single biggest drivers across all medical technology organisations (Topham, 2003). The European Union's regulatory system for medical devices has proven highly successful, and is recognised as providing the 'gold standard' globally; it has demonstrated its efficiency in rapidly bringing the benefits of innovation to people. According to independent studies, people in the European Union on average benefit from advances in medical technology 3-5 years earlier than in Japan and 3 years earlier than in the US, without compromising safety (EUCOMED, 2014). By avoiding excessive delays, the European regulatory system provides an incentive for innovation. Designers and manufacturers are encouraged to develop better products that address patient and healthcare needs more quickly.

In 2013, over 10,000 patent applications were filed with the European Patent Office in medical technology. 41% of these were filed from European countries (EUCOMED, 2014). In terms of context, in the same period around 5400 applications were filed in pharmaceutical fields and 5400 in biotechnology (European Patent Office, 2014). The current economic troubles within European Union members will likely result in slow market growth from 2014-2019, especially within southern European states. With the increased regulatory challenges with recent and forthcoming regulation, medical device manufacturers in Britain will face increased cost-containment measures, and focus on smaller areas in order to show business growth. This is at the cost of innovation. As a result of recent and very public

failings (e.g. PIP and metal-on-metal hip), European Legislation has already responded with Notified Bodies affording more control and longer review times – which is paid for by manufacturers. Although you can not legislate to prevent law being broken, the new legislation is set to offer a more rigorous, but more transparent review of medical device manufacturers where stricter and more detailed monitoring and enforcement activities from both Notified Bodies and National Competent Authorities (like the MHRA in the UK). More stringent approval procedures with additional clinical evidence requirements for high-risk devices will also increase the regulatory burden on manufacturers. Longer and more costly approval procedures threaten to undermine the competitiveness of the European medical device industry, which comprises largely small and medium-sized companies (Klien, 2014) (Topham, 2003). Intellectual Property is also protected by a single EU catch-all, with single cost and single registration for UK IP providing protection throughout Europe.

The financial support provided by the EU has allowed organisations to develop test methods, and work in collaboration with UK universities to conduct highly specialised tests, and collaborative work. However, the de minimis restrictions results in a reduction of the total collaboration possible for UK business – as such use of this valuable resource funding is restricted. But certainly without this funding from the EU many organisations could not bring as many healthcare innovations to the European market.

UK Landscape for Medical Technology.

In Britain, medical technology companies make a vital contribution to the British economy. With over 3000 companies employing 76,000 people the sector is valued at some £17 billion

and growing at rates exceeding 6% (Association of British Healthcare Industries, 2015). The UK is the second highest employer of medical technology companies, beaten only by Germany.

A significant proportion of companies are working closely in partnerships with UK Universities and research institutes resulting in close collaboration and rapid development of ideas into inventions, and subsequently onto market. There is significant investment from Government, including Knowledge Transfer Partnerships that seek to facilitate the cross-pollination of skills from academia to industry and visa versa. Furthermore, the UK's National Health Service is dependent on British business to improve treatments, diagnostics, service enhancements and the like to drive continuous improvements in both budgetary controls and patient wellbeing.

It is estimated that 38 million people contact a medical device every day in the UK (SEHTA). In 2000, the Global market for medical technology stood at £118 billion, with Europe accounting for 25% of that total. The UK medical device market makes up 12.8% of the Western European market and 3.3% of the world market. The UK market continues to be one of the strongest performers in the region, with growth of around 6.8% per annum forecast to 2018. There are around 500,000 medical technology products, grouped into 20,000 groups available today (EUCOMED, 2014). These technologies rely on multi-disciplinary experts including; regulatory & legal, electronics, mechanical engineers, polymer science, chemistry, biochemistry, optics, software and more.

The United Kingdom exports 5 billion Euros outside of the European Union (Epsicom, 2014). American industry supplied 25 percent of imports and accounted for 12 percent of the total \$3.4 billion medical equipment market in Britain in 2002 (Topham, 2003). Current market growth has been slow, and the lack of domestic investment in new product development in recent years has created a demand for imported high-tech equipment. Requirements include lasers, endoscopes, medical imagery and dental equipment.

The UK market is dominated by the NHS, which accounts for more than 80% of expenditure (Association of British Healthcare Industries, 2015) (Klien, 2014). The private sector remains small—if well equipped—and largely based in England. The reorganization of the NHS under the Health & Social Care Act 2012 has already seen a structural shift; Primary Care Trusts have been abolished and replaced by Clinical Commissioning Groups, giving general practitioners a greater role in budgeting and, therefore, spending.

The innovation that Britain is famous for is supported by systems which encourage and support small and medium sized enterprise (SME), which we all benefit from in both improved health care and economically (Browning, 2014). That is not to say the system is perfect, far more needs to be done to improve the efficiency and effectiveness of innovation to commercialisation.

Development of improved medical devices supports improved health in the British population, and good health is a prerequisite for well-being and economic prosperity. These medical technologies help people live longer, healthier, more productive, socially active and independent lives. This includes improved employability, where medical technology contributes to ensuring economic growth through improved workforce health.

Conclusions:

Remaining a member of the European Union will enable UK industry to take advantage of the existing regulatory structure and not be required to develop or change it to fit a new set of regulations. Although the current European medical device regulation is already costly and difficult for UK innovation, and the draft legislation will further increase the control, scrutiny and enforcement at a potentially large cost to UK industry, this is being carried out in the interest of patient safety.

The European approach still offers a faster, cheaper alternative to the certification routes of other countries in the world market. It is worth considering that, although the EU regulation is increasing control, so is the rest of the world. It is becoming even more difficult to bring new devices to market in places like the US and Japan, where it is already a challenge for small and medium-sized manufacturers to meet the cost of testing and application fees, let alone the regulatory burden of the process.

Due to the high cost of these other systems, emerging countries, starting their journey on medical device regulation, are adopting either the basis of EU conformity, or a variation thereof. The benefit of the risk based assessment of medical technology is recognised and the needs of the country are adequately met by a system that does not restrict the development of innovative technology to the manufacturers that are already large and successful.

Compliance to the appropriate EU legislation via the CE route of conformity enables unrestricted trade for UK industry throughout Europe. This is of huge benefit to the European market, allowing consumers access to a wide variety of technology and treatment options whilst also granting manufacturers access to as many markets that their devices can apply to without unnecessary regulatory burden, low costs and short waiting time. A large number of other countries accept CE conformity for medical devices, allowing a simpler and less financially challenging route to these markets as well.

The European Medical Device Regulations provide the ideal mix between control and innovation, ensuring citizens of Europe are afforded faster access to new healthcare technologies and that even the smallest manufacturer can create the next innovative technology, while maintaining the focus on patient safety through risk assessment and mitigation.

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Conflict of interest statement

Both authors are employed by Brightwake Ltd, an innovative medical device company.

Paul Browning holds a research position at the University of Worcester