Association of British Healthcare Industries response to the Science and Technology Committee inquiry into the regulation of medical implants

About ABHI
The Association of British Healthcare Industries (ABHI) is the industry association for the medical technology sector in the UK. ABHI’s mission is to champion the benefits and use of safe and effective medical technologies to deliver high quality patient outcomes. With over 240 members, ABHI leads the advocacy of the industry in order to advance access to medical technology. Its membership includes many UK small and medium sized enterprises (SMEs) and some of the leading multinational businesses in the sector.

Executive Summary
- Implantable medical devices provide benefits to millions of people in the UK.
- Medical devices are regulated under the Medical Device Directives. It is important that the legal frameworks governing their introduction to the market maintain the highest standards of patient safety.
- The current system has been in place for twenty years, and like any regulatory regime dealing with innovative products it needs regular revision. This process is currently underway.
- The medical device industry supports the process of revision and has suggested a number of amendments to the system around the following areas:
  - Notified Bodies
  - Vigilance and post market surveillance
  - Clinical Evaluation
  - Mechanisms for consistent implementation
  - Unique Device Identification
  - Confidentiality
  - Coordination and management
- The medical device industry firmly believe that if the changes outlined below, in particular those around Notified Bodies, vigilance and consistency, are enacted and implemented Europe will have a system which continues to support the development and introduction of innovative medical devices that will continue to improve the lives of people across the UK whilst improving patient safety.

1. Introduction and Overview
Millions of people in the UK benefit from implantable devices. For example, each year over 150,000 people in the UK receive artificial knee and hip joints (National Joint Registry, 2011). Implants enable patients to continue to live fulfilling working and family lives, and prevent their premature withdrawal from the labour market. In 2009 it was estimated that 11,000 people were able to return to work following a total hip or knee replacement, saving the welfare system £37.2million (Bevan et al, 2011).

2. The term ‘implant’ covers products ranging from active (i.e. powered) implants such as pacemakers to non-active implants such as joint replacements. These products are regulated in the UK under the Medical Device Regulations 2002 which transpose three main European Directives

   a. Directive 90/385/EEC on active implantable medical devices (AIMDD)
b. Directive 93/42/EEC on medical devices (MDD)

3. The term medical device covers a vast range of products ranging from syringes to scanners. Only a small proportion of these products are implants. Medical devices are central to the operation of all health systems. They enable clinicians to carry out procedures, facilitate the effective operation of the hospital infrastructure and are often used in the home by patients themselves.

4. **How the current legislation delivers innovation to patients**

   Medical devices are regulated under the Medical Device Directives. The products regulated by these directives play a crucial role in keeping the UK population healthy and productive by supporting innovation in healthcare, while also contributing to the UK knowledge-based economy. The UK medical device sector employs 64,000 people in the UK and is a key part of the UK life science industry that was described by the Prime Minister as the “jewel in the crown of our economy” (Department of Business, Innovation and Skills, 2011). The medical technology sector’s contribution to safe, efficient and life-enhancing products and services is based on its capacity to innovate.

5. The Medical Device Directives ensure that patients receive treatment from safe products which have undergone a thorough compliance process. At the same time, they enable the free movement of product between EU member states.

6. The Directives were first developed in the 1990s under the framework of Europe’s “New Approach” (today replaced by the New Legislative Framework) in response to the threat of proliferation of different regulatory systems around Europe and the need to protect public health.

7. As with any regulatory regime that deals with a large range of products the Medical Device Directives use a classification system. This system classifies devices by risk with the lowest risk devices being in category I and the highest risk devices falling into category III. Implantable products are subject to the most rigorous controls and therefore attract the most stringent compliance rules. However any consideration of the regulations covering implants must also address the entire framework of device regulation.

8. Following extensive consultation with all stakeholders the European Union issued a Council Conclusion in June 2011 which reaffirmed European Member States commitment to the current legal framework. This capacity is in turn dependent on an effective and efficient EU-wide regulatory framework.

9. This framework needs to provide for patient access to safe, high quality healthcare products while allowing for the timely introduction of innovation. Indeed good regulation should be supportive of innovation which can deliver safer more effective products; to stifle innovation would stifle this cycle of improvement and delay patient access to potentially lifesaving innovations.

10. We therefore believe the current regulations have been instrumental in safeguarding patients whilst bringing them medical benefits. Like any system it is important that there is a regular review to identify potential improvements. There have been very few instances of product failure when one takes account of the many millions of products used annually- it is estimated 38 million people come into contact with a medical device every day (SEHTA, 2011).
11. The system is currently under review and the resulting Revision will be the subject of an EU Commission ‘Formal Proposal’ in mid 2012. ABHI and the medical technology industry fully support the need for changes to the system.

12. **The role of the MHRA**
   We believe that the MHRA does a very effective job in implementing the Directives. It is indeed often considered to be the pre-eminent Device authority in the EU and is well respected throughout Europe and beyond among those concerned with efforts to achieve global harmonization in device regulation.

13. **How can the legislation and regulations be improved?**
   The system is currently under review. During wide consultation by the EU Commission a number of potential improvements were identified. The UK medical device industry believes the system should:
   - be robust and comprehensive
   - protect public health and enable efficient healthcare delivery
   - enhance public confidence whilst avoiding unnecessary bureaucracy
   - be consistent and transparent
   - effectively foster and support innovation

14. The following points will explore this, addressing the areas where we believe reform is necessary.

15. **Notified Bodies**
   Notified Bodies are independent third parties nominated and monitored by Member State Competent Authorities, such as the MHRA. Therefore, they act on behalf of the member state authority that has designated them. They carry out pre- and post-market scrutiny and certification of medical devices. The operation and coordination of Notified Bodies is an area that industry would like to see improved as part of the Revision. As structured today, the control and oversight by National Competent Authorities of their Notified Bodies depends largely on voluntary and national approaches rather than on consistent, mandatory EU level rules and standards.

16. We therefore believe that Notified Bodies which are central to the New Approach system have not been designated or controlled with sufficient rigour and that this aspect of the device regulatory system must be improved. Steps are already being taken by the EU Commission as part of a series of short term measures requiring Competent Authorities to review the designation of Notified Bodies. This, together with the development of better control mechanisms, must feature in the Revision. Policy makers should focus on oversight of notified bodies’ performance, rather than introduce further steps in the regulatory process. There are currently c.80 Notified Bodies across Europe and we believe that a more robust approach to designation should result in a significant reduction.

17. **Vigilance and post market surveillance**
   These are key features of the system and are central to its improvement in the future. The sharing of data between Member States is crucial for patient safety; there must be a cross border communication system that facilitates the efficient transfer of information between national Competent Authorities. The current regulatory framework for medical devices requires vigilance and market surveillance systems to be put in place by manufacturers and national Competent Authorities. This is intended to allow for rapid identification and response in case of incidents which may put patient or user safety at risk or create doubt about the product performance. At present however, there is a lack of coordinated exchange of information on reported incidents as well as considerable variation in how different EU Member States respond to incidents. This has resulted in both duplication of effort and inconsistencies.
18. A better defined legal framework on vigilance and greater harmonisation of Member States’ market surveillance activities are therefore needed to ensure rapid and consistent EU-wide risk identification and response. This would deliver significant benefits for overall patient safety allowing centralised reporting and surveillance, using an EU portal for reporting.

19. **Clinical Evaluation**

Clinical evaluation of a device is required when demonstrating conformity with relevant essential requirements. For medical implants, this process is particularly important, as the characteristics of a device when implanted in the body need to be understood and documented. ABHI believes the revision of the MDDs should see the system become more prescriptive in setting out when manufacturers need to undertake clinical investigations, or to what extent they are able to rely on existing scientific literature claiming equivalence with an existing device.

20. Notified Bodies are responsible for assessing clinical evaluation by manufacturers as part of conformity assessment, ensuring that appropriate clinical investigations have taken place. ABHI therefore believes that by improving the coordination of Notified Bodies, the scrutiny of clinical evaluation will be greatly improved.

21. **Mechanisms for consistent implementation**

Currently, the European Commission, in consultation with Member States and affected stakeholders, issues guidelines aimed at supporting consistent implementation and interpretation of the Medical Devices Directives. However, the process leading to development or revision of these guidelines lacks pace and legal certainty. In addition, when the guidelines are finalised and agreed, evidence shows that there are severe disparities in the way and extent to which they are implemented in the Member States. This has led to significant cross-border variations in terms of quality of conformity assessment procedures, lack of process clarity and predictability for manufacturers and national responses to vigilance.

22. These cross-border disparities must be addressed in the Revision by changing the current procedure for development of guidelines. This needs full commitment from Member States in order to use clearly defined and transparent drafting procedures, including timelines. This must involve all stakeholders including the European Commission to ensure coherence with European law.

23. **Confidentiality**

The confidentiality requirements under the current Medical Devices Directives are seen by some stakeholders as being too restrictive (e.g. in terms of access to information about products on the market, or the functioning and decision-making of Notified Bodies).

24. The Revision of the EU legislative framework for medical devices must result in greater overall transparency and access to information for patients, consumers, healthcare professionals and manufacturers as well as for Notified Bodies, national Competent Authorities and the European Commission.

25. **Unique Device Identification**

Unique Device Identification (UDI) is a requirement for all devices to carry a machine readable identifier (today probably a bar code but this may change as other technology becomes available). This requirement will be included in the Revision and will be a significant step in the quest to improve patient safety. UDI will enable a particular implant to be linked to the patient who receives it and will
greatly assist in the setting up of databases and registries. UDI will be based on internationally accepted standards and will eventually become a global requirement for devices as it is also the subject of legislation in North America, Australia and other regions.

26. **Coordination and Management**

Today the EU oversight of medical devices is decentralised and this European approach makes it possible to manage what is a highly innovative and diverse industrial sector in terms of products, technologies and services. The decentralised approach is best placed to provide the capacity to efficiently deal with the many applications related to over 400,000 products on the market from over 22,000 medical technology businesses, 80% of which are SMEs.

27. The decentralised approach, which is the essence of the current system, should remain a basic principle of the future legislative framework for medical devices in order to preserve safety, flexibility and pace. However, the current system does suffer from disparate national approaches. It needs improved coordination at EU level to ensure uniform application by Member States, especially in the areas of Notified Bodies and vigilance.

28. **How could the European Commission ensure that potential changes to the Medical Devices Directive do not hinder the introduction of innovations in medical implants to the market?**

As stated above the medical device directives have been instrumental in safeguarding patient safety whilst bringing them medical benefits. The current system allows patients to access innovation at the appropriate time.

29. We firmly believe that if the changes outlined above, specifically those around Notified Bodies, vigilance and consistency, are enacted and implemented Europe will have a system which continues to support the development and introduction of innovative medical devices that will continue to improve the lives of people across the UK whilst maintaining patient safety.

**Bibliography**


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