January 2013

**Joint submission to the MHRA consultation on the ‘Revision of European Legislation on Medical Devices’**.

1. Arthritis Research UK and the British Orthopaedic Association (BOA) welcome the opportunity to respond to the Medicine and Healthcare products Regulatory Agency (MHRA)’s current consultation on the Revision of European Legislation on Medical Devices.1 We have chosen to submit a joint response, as we both take a keen interest in the treatment of patients by orthopaedic surgeons, many of whom receive joint replacements and/or other implants. We seek in this response to represent the views of the surgeons and their patients, with whom we both work closely. While both of us, and particularly the BOA, already work with the MHRA in this area, we are pleased to have this opportunity to provide further input to your work in engaging with the Commission as the legislative process proceeds.

2. The BOA is the Surgical Specialty Association for Trauma and Orthopaedics in the UK. We have over 4000 members worldwide, the majority based in the United Kingdom and Ireland. Membership is made up of Consultants (active or retired), Surgeons in training and Staff and Associate specialist grades (SAS). As a membership organisation we care for patients and support surgeons by focusing on excellence in:
   - Professional Practice
   - Training and Education
   - Research.

Joint replacement and implant surgery is a core area of our members’ work. We therefore take a keen interest in this, and have had significant involvement in several related initiatives, including ‘Beyond Compliance’ and registries such as the National Joint Registry (NJR) and the Scottish Arthroplasty Project (SAP).

3. Arthritis Research UK is the UK’s fourth largest medical research charity. Our vision is ‘a future free from arthritis’. Our remit includes arthritis and musculoskeletal conditions, which are disorders of the joints, bones and muscles – including back pain – along with rarer systemic autoimmune diseases such as lupus.2 Together, these conditions affect around ten million people across the UK and account for the fourth largest NHS programme budget spend of £5 billion in England.3,4 Arthritis is the biggest cause of pain and disability in the UK, and each year 20% of the general population consult a GP about a musculoskeletal problem such as arthritis.5 In 2011, 98% of primary total knee replacements carried out in England and Wales were owing to osteoarthritis.6 As a charity we fund research, provide information to patients and educational resources for healthcare professionals.

4. This response addresses aspects of the MHRA’s consultation which relate to the draft medical devices regulation (and not the draft *in vitro* diagnostic devices regulation). We have focused on the following areas:

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3 The NHS Atlas of Variation in Healthcare, Right Care, November 2011
4 NHS programme budget spend for 2010/11.
5 *Musculoskeletal Matters*, Arthritis Research UK National Primary Care Centre, Keele University, October 2009
5. **Overview**

The existing EU regulatory framework for medical devices is based on two Council Directives (90/385/EEC on active implantable medical devices and 93/42/EEC on medical devices). There have been significant advances in medical device technology since the adoption of these Directives, and the Commission recognises that there has been increasing divergence in the application of legislation for medical devices across a growing number of European Union (EU) member states over time.

The aims of the proposed regulation, which would replace both Directives, are to: strengthen patient safety, address regulatory gaps or uncertainties, promote harmonisation across Europe, ensure innovation and competitiveness of the medical devices industry and allow free movement of medical devices across the EU single market.

We are very much in favour of the aims of improving patient safety and addressing regulatory gaps or uncertainties.

We note that the UK has already several bodies and initiatives in place regarding the monitoring and safety of joint replacement and implants, and highlight two of these at the outset.

Firstly, we highlight the National Joint Registry (NJR), which collects data on hip, knee, ankle, elbow and shoulder replacement operations in England and Wales and monitors the performance of joint replacement implants as well as the surgeons involved in the operation. The NJR already holds information on approximately 60,000 components. For total joint replacement, we believe the NJR has the most sophisticated component database in the world, and it is presently linking with the Australian and Norwegian registries to start putting together what is hoped will be an international system. In Scotland, the Scottish Arthroplasty Project (SAP) undertakes some of these functions, and a Scottish Joint Registry is under consideration.

Secondly, we highlight the Orthopaedic Data Evaluation Panel (ODEP), which has an important role in benchmarking prostheses and publicising their ratings. Manufacturers are requested to keep ODEP informed of all commercially available prostheses that are involved in post-market clinical follow-up studies. The BOA is fully engaged in both these initiatives and considers that they are well established and as such play an important part in the current landscape of device safety and monitoring in the UK.

We feel it is important that the work that has gone into establishing these initiatives must not be lost through the introduction of any new or revised systems. Consideration should be given as to how they may be integrated or built upon in any future systems. Several NICE guidelines also relate, of which MHRA should also be aware.

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7 The European Commissions has also published a proposal to replace the related Directive98/79/EC which relates to *in vitro* diagnostic medical devices.
9 National Joint Registry for England and Wales, 9th Annual Report, 2012
10 For example guidance on primary total hip replacement: [http://guidance.nice.org.uk/TA2](http://guidance.nice.org.uk/TA2)
6. **Implant cards**
Under article 16 of the draft regulation, manufacturers of an implantable device would be required to provide an implant card to patients implanted with a medical device. The card would be written so that it could be understood by a lay person and would contain:

- Information allowing identification of the device, including the Unique Device Identification (UDI);
- Warnings, precautions and measures to be taken by the patient or a health professional;
- Information about the expected life-time of the device and any follow-up.

We agree with the MHRA that implant cards will be helpful in improving patients’ awareness of the implants they have received, and that they may also help to increase traceability of medical devices.

We agree that, where a device containing a number of components is implanted in a single operation, it could be helpful for the patients to receive this information in a consolidated form, rather than as a large number of individual cards. Another example is in polytrauma, where a person may receive a number of implant systems during a single operation.

A simple solution may be to create combined cards which carry UDI information for all the components used in a particular operation – for example a ‘hip operation’ card. This would be comparable to the process currently used during surgery where a label for each component is attached to the operation notes creating a single record.

7. **Unique Device Identification (UDI)**
Article 24 of the draft regulation describes a system for Unique Device Identification which would be put in place allowing the identification and traceability of devices throughout the EU. The UDI system would involve the placement of a unique code on each medical device. Codes would be recorded by economic operators (e.g. device manufacturers, importers and distributors), health institutions and included in the technical documentation produced by manufacturers when reporting incidents. A central database (the European databank) would be established to store UDI information.

We agree with the MHRA’s view that the development of a European Union-wide system of UDI is a welcome and significant aspect of the draft regulation.

A UDI system is already in place for many orthopaedic implants within the UK; the National Joint Registry (NJR), as mentioned above, collects data on hip, knee, ankle, elbow and shoulder replacement operations and monitors the performance of joint replacement implants as well as the surgeons involved in the operation. The NJR’s component database uses a unique code for each type of implant.11

The MHRA should carefully review which aspects of the UDI system will be delegated to the Commission for decision, and should consider the compatibility of a European system with existing systems in the UK. This will be a particularly important issue for the UK, given that a well-developed system is already in place, that this already has considerable historical data within it, and that it is making a contribution to post-market surveillance of joint replacement devices. In particular we note its involvement in the identification in 2010 of the poor performance of the Depuy ASR hip prosthesis, leading to the voluntary worldwide recall of the device by the manufacturer.12

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Areas for further consideration and clarification in relation to UDI include:

- How the proposed European UDI system will be applied to devices which have some components parts that remain outside the body (e.g. external fixators, or Ilizarov frames which are used to treat complex or open bone fractures). We suggest that components of medical devices which are not directly implanted within the body should not carry a Unique Device (UD) identifier.

- How the proposed European UDI system could best be developed to provide for implants with large number of components parts, each of which may carry a UD Identifier (e.g. implants used in trauma and spinal surgery), without undue administrative burden.

Consideration should be given to the practicalities of establishing a central database, as this is likely to involve significant administrative effort. There is a need for further clarity on areas including:

- Consent and confidentiality. Appropriate procedures would need to be established to seek the consent of implant recipients for the collection and storage of their personal data. Adequate measures must be in place to ensure confidentiality and security of personal data.

- Accuracy and maintenance; to support traceability there would be a need to determine how contact details of implant recipients can be updated and accuracy maintained over time.

- Proportionality and simplicity; consideration should be given to compatibility (and data linkage) with existing databases to avoid the need for repeat entry of data.

- Who will bear the cost of the database, including its establishment and on-going upkeep and maintenance?

As mentioned above, the NJR is presently linking with the Australian and Norwegian registries to start putting together what is hoped will be the international UDI system, and we would suggest that this work could provide the groundwork for any European system. We are aware that the NJR would almost certainly welcome the opportunity of sharing their expertise and experience with Europe.

8. Clinical evaluation

Chapter VI (Articles 49-60, together with Annexes XIII and XIV) of the draft regulation sets out the obligations of manufacturers in demonstrating the safety and performance of their medical devices, including through both pre-market clinical evaluation and post-market clinical follow up. The process for conducting clinical investigations using medical devices (the equivalent of a ‘clinical trial’ for a medical product) is detailed.

We agree with the broad principle proposed by the MHRA, that changes introduced in the draft regulation to improve the standards of clinical evaluation by manufacturers, and the assessment of clinical evidence by notified bodies, should be supported. However, it is important to ensure that the regulatory and reporting requirements for clinical investigations do not become overly complex and so a deterrent to those seeking to conduct them.

The MHRA should carefully review the proposed roles of the Commission and of ‘coordinating competent authorities’ in relation to clinical investigations. Although central bodies may have an important role as information repositories, and in information sharing, it is important for aspects of decision-making (for example the power of national authorities to take action on device manufacturers) to remain at a national level.
In relation to the provision of evidence for clinical evaluation of new devices coming onto the market, and for post-market surveillance of existing devices, we highlight two initiatives which are underway:

1. The BOA and MHRA are currently working together, through the ‘Beyond Compliance’ initiative, to consider the system for the introduction of new joint replacement implants (particularly hip and knee) and their monitoring in the UK. The overall aims of this work are to increase the availability of short- to mid-term clinical data and to strengthen the evidence base for new implants in a more transparent manner.\(^\text{13}\)

‘Beyond Compliance’ has sought to address three main processes:

- 1. Improving the rigour of processes around CE marking before an implant is sold, by offering good quality advice.
- 2. Providing guidance and support for the safe and agreed introduction of innovations.
- 3. Providing high quality surveillance and a decision making process to identify failures at the earliest point and suggest appropriate actions.

‘Beyond Compliance’ promotes the concept that the safest, best and most successful systems are those that go beyond compliance with minimum regulatory requirements. It makes proposal for a voluntary system which would work within existing mandatory regulatory requirements.

We consider it is important that the work that has gone into establishing this initiative must not be lost through the introduction of any new or revised systems. Learning from this UK initiative will be helpful in informing development of this area of the draft regulation.

2. In 2012, Arthritis Research UK convened an expert group (whose membership includes the BOA president) to consider the research required to provide clearer scientific understanding of metal-on-metal joint replacement, including any possible long term hazards. The group will highlight the key research questions around this type of hip joints, and are working to identify and prioritise a future research agenda.\(^\text{14}\)

9. \textbf{Classification}

The draft Regulation retains the established approach for the classification of medical devices into four levels according to their intended purpose and risk (I, IIa, IIb, and III, with III the highest risk). This approach is currently used both within Europe and internationally. However, there are some proposed changes to the existing EU classification for different types of device in the draft regulation, according to the definitions and rules set out in Annex VII. Specifically, Annex VII Rule 8 states:

- “All implantable devices and long-term surgically invasive devices are in class IIb unless they: …
  - are hip, knee or shoulder total and partial joint replacements, in which case they are in class III, with the exception of ancillary components such as screws, wedges, plates and instruments,
  - are spinal disc replacement implants and implantable devices that come into contact with the spinal column, in which case they are in class III.”

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\(^{13}\) More information about the Beyond Compliance project is available online at: https://www.boa.ac.uk/LIB/LIBPUB/Pages/Beyond-Compliance.aspx. The ‘Beyond Compliance’ project steering committee is chaired by the BOA’s past-president Peter Kay

There are two points we would emphasise here:

- We support the re-classification of spinal disc implants bringing this form of implant within class III.
- We strongly feel that in addition to hip, knee or shoulder total and partial joint replacements being classified as class III, this should apply to all joint replacements, including those in the hand, wrist and ankle. We suggest this because replacements involving the hand, wrist and ankle have similar risks to those for hips and knees and have much higher failure rates.

10. Contributors and contact details

We are very grateful to the following for contributing to this response:

- Mr Anthony Hui, South Tees Hospitals NHS Foundation Trust
- Mr Keith Tucker, BOA member, former Council member and Chairman ODEP
- Mr Peter Kay, Wrightington Hospital, Former President BOA
- Professor Damien Griffin, Chair, Arthritis Research UK Orthopaedic Clinical Study group
- Professor Joe Dias, Past President and Chair of Professional Practice Committee, British Orthopaedic Association.

We hope this joint response is helpful. Please contact us at the addresses below if require further information.

Yours sincerely,

[Signatures]

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