14 October 2011

Committee Secretary
Senate Standing Committee on Community Affairs
PO Box 6100
Parliament House
Canberra ACT 2600

By email: community.affairs.sen@aph.gov.au

Dear Committee Members

Senate Inquiry into the Regulatory Standards for the Approval of Medical Devices

The Community Affairs Committee conducted a hearing on 27 September 2011 as part of the Inquiry into the Regulatory Standards for the Approval of Medical Devices.

Johnson & Johnson Medical Pty Limited (JJM) appreciated the opportunity to make a submission to the Committee and to attend the hearing. During the hearing, certain questions were taken on notice and we provide information in relation to those questions below.

We have endeavoured to provide concise responses to the questions taken on notice as we understood them (and in accordance with the Hansard Transcript). We note that certain questions relate to matters which are currently before the Courts and, as it would be inappropriate for us to comment in light of the litigation ongoing both in Australia and overseas, we have provided as much information to the Committee as possible within those constraints.

1. The date on which Johnson & Johnson Medical Pty Limited (JJM) became aware that there was a higher rate of revision than was anticipated in the ASR products (in relation to the Australian Orthopaedic Association (AOA) National Joint Replacement Registry (NJRR) 2006 Annual Report).

DePuy Orthopaedics Inc (DePuy) and Johnson & Johnson Medical Pty Limited (JJM) engage in ongoing post-market surveillance which involves continually evaluating data from a variety of sources, including that provided by registries.

In relation to the AOA NJRR 2006 data, the report produced by the AOA NJRR 2006 stated that the revision rates for the ASR products were not a significant issue. Specifically, with respect to the resurfacing product, the report stated:

> *The ASR has a higher revision rate when compared to the [Birmingham Hip Resurfacing] but it is not significant.*[1]

[1] Page 57 of Australian Orthopaedic Association Annual Report 2006, available at: http://www.dmac.adelaide.edu.au/aoanjrr/documents/aoanjrrreport_2006.pdf.

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The revision rates reported in 2010 by the UK National Joint Registry were higher than expected, which resulted in DePuy Orthopaedics Inc (DePuy) issuing a voluntary recall of the ASR Hip System on 24 August 2010. For your reference, below is an extract from the recall notice which sets out the revision rates known to DePuy Orthopaedics Inc (DePuy) at the time:

> *DePuy Orthopaedics issued a Field Safety Notice in March 2010 after receiving new data from the UK that demonstrated that the ASR System had a higher than expected revision rate at 8-9 percent at three years when used with smaller head sizes (less than 50 mm diameter). The overall revision rate for ASR continued to be in line with the class of metal-on-metal monoblock systems based on the data available to DePuy at the time.*
>
> *DePuy has just received new, unpublished 2010 data from the National Joint Registry (NJR) of England and Wales. The data shows the five year revision rate for the ASR HIP Resurfacing System is approximately 12 percent and for the ASR XL Acetabular System is approximately 13 percent. These revision rates are across the entire size range. The risk for revision was highest with ASR head sizes below 50 mm in diameter and among female patients.*
>
> *Because the new NJR data shows a higher than expected revision rate at five years, DePuy is issuing a voluntary recall of all ASR products.*

2. Details of the Crawford & Company process.

Our first priority is the care and wellbeing of all ASR patients. We want to make sure that ASR patients are well informed and receive the information and support they need during this difficult time. As such, we have established a compensation process with Crawford & Company (Australia) (Crawford & Company) to assist patients. Crawford & Company provides reimbursement for:

- expenses incurred by patients for tests and treatment; and
- out-of-pocket expenses.

As mentioned during the hearing, in certain circumstances, Johnson & Johnson Medical Pty Limited (JJM) may provide additional compensation on a case by case basis.

We set out below further details of the Crawford & Company process and the further compensation referred to above.

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2.1 ASR Help Line and Crawford & Company scheme.

Crawford & Company has been engaged to process the funding of reasonable and customary expenses incurred by patients for tests and treatment (including revision surgery) associated with ASR hip devices. The expenses funded include hospital charges, surgeon and anaesthetist fees, surgical assistant fees and implant costs, and out-of-pocket costs for reasonable and documented expenses, such as travel expenses, subject to review by Crawford & Company.

Patients (or someone on their behalf) should call the ASR Help Line operated by Crawford & Company on 1800 665 460. They will be asked to fill out a form consenting to their medical records being shared with DePuy Orthopaedics Inc (DePuy) and will need to provide some information about their hip replacement surgery which will help DePuy Orthopaedics Inc (DePuy) confirm whether the patient has an ASR implant (eg the date of surgery, the surgeon and hospital). The patient's surgeon will also need to provide information to DePuy Orthopaedics Inc (DePuy) which will require the patient giving DePuy Orthopaedics Inc (DePuy) permission to speak with them about their surgery.

Upon confirmation that a patient has an ASR implant, DePuy Orthopaedics Inc (DePuy) will aim to provide pre-approval costs and arrange for healthcare professionals to send their tax invoices directly to Crawford & Company for discharge on behalf of DePuy Orthopaedics Inc (DePuy).

DePuy Orthopaedics Inc (DePuy) will arrange for Crawford & Company to send the patient a letter containing an ASR Claim number and instructions for healthcare professionals authorising them to send the invoice for their service directly to Crawford & Company for payment. If patients have already paid for testing services or have incurred out of pocket expenses associated with testing, the patient can send the bills to the ASR Help Line and Claims Centre for review and processing.

Further information relating to the recall process is available for patients and surgeons at http://asrrecall.depuy.com/aurecallguide .

2.2 Further compensation.

As referred to at the hearing, for patients who are assessed to be eligible for funding under the Crawford & Company process, Johnson & Johnson Medical Pty Limited (JJM) may consider providing additional compensation (on usual terms) over and above the Crawford & Company funding, having regard to the individual's particular circumstances. Such consideration is likely to be most appropriate for patients whose conditions have stabilised. Those individuals (or someone on their behalf) should approach Johnson & Johnson Medical Pty Limited (JJM) directly.

Any compensation provided beyond the Crawford & Company process would be on a full and final settlement basis and covered by a settlement agreement.

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3. How long a company has to respond to a Therapeutic Goods Administration suggestion or notice that a product be withdrawn.

The Therapeutic Goods Administration (TGA) is in constant dialogue with product suppliers in relation to recall strategies. What is considered to be a reasonable time period for withdrawing a product will vary with each product and circumstance, regardless of whether the recall is voluntary or mandatory.

Most recalls are conducted on a voluntary basis and the sponsor has the key responsibility for implementing the recall and ensuring compliance with the recall procedures. In such cases:

- if there is a problem with a medical device or the way in which it is being used, the sponsor and manufacturer will first conduct an analysis and make a decision on the appropriate action;
- such action may require notifying or obtaining further advice from the Therapeutic Goods Administration (TGA) in relation to undertaking corrective or preventative actions, informing users, and removing the device from the market;
- when the need for a recall has been established, information should be provided to the Therapeutic Goods Administration (TGA) so that an appropriate recall strategy can be devised by the sponsor and the Therapeutic Goods Administration (TGA); and
- in discussing a recall strategy, the sponsor and Therapeutic Goods Administration (TGA) recall coordinator will consider the factors which may affect the duration of the recall action and the completion date.

If a recall is initiated under section 41KA of the Therapeutic Goods Act 1989 (Cth) a supplier may be required to take particular steps to recover the medical devices and inform the public within a reasonable time. The manner in which such steps are taken, and what is considered to be a reasonable time, will be specified in the recall notice and will vary with each recall, depending on the nature of the medical device being recalled and the circumstances necessitating the recall.

A mandatory recall may also be initiated under section 122 – 123 of the Australian Consumer Law where a product may cause injury to a person and if a supplier has not taken satisfactory action to remove the hazard created by the products. If a compulsory recall notice is issued, the notice may specify the manner in which the required action must be taken and the time period for such action. Again, there is no prescribed time for recalling the products and the specific requirements for the recall will be set out in the notice.

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4. Whether Johnson & Johnson Medical Pty Limited has any procedures relating to what course of action is taken when the Therapeutic Goods Administration suggests a recall.

Johnson & Johnson Medical Pty Limited (JJM) devises and manages internal procedures for handling recalls of its products. In particular:

- Johnson & Johnson Medical Pty Limited (JJM) has a Standard Operating Procedure (SOP) for managing recalls; and
- The Therapeutic Goods Administration (TGA) has a procedure for managing recalls. This is governed by the Uniform Recall

Procedure for Therapeutic Goods, available at: http://www.tga.gov.au/pdf/recalls-urptg.pdf.

If either Johnson & Johnson Medical Pty Limited (JJM) or the Therapeutic Goods Administration (TGA) initiates a recall, the procedures set out above would be followed. The Johnson & Johnson Medical Pty Limited Standard Operating Procedure specifically refers to the Uniform Recall Procedure for Therapeutic Goods.

More information in relation to the complaints handling and adverse events reporting conducted internally at Johnson & Johnson Medical Pty Limited (JJM) is set out in Section 7 below.

5. The differences in meeting both the approvals and monitoring of pharmaceuticals and medical devices

As you will appreciate, and as the question anticipates, what is provided below is necessarily only a broad overview. Should you require any further or more detailed information, please let us know.

All therapeutic goods (including medical devices and medicines) must be included in the Australian Register of Therapeutic Goods (ARTG) before they can be imported or supplied in Australia, or exported from Australia, unless the goods are exempt or excluded. Although the particular listing or registration requirements and conditions vary depending on the product type and category, in broad terms, the Therapeutic Goods Administration (TGA) requires information on the quality, safety and efficacy of a product or device and evidence that the product or device has been manufactured in accordance with appropriate standards in order for it to be included on the Australian Register of Therapeutic Goods (ARTG), as set out in http://www.tga.gov.au/industry/compliance-with-standards.htm.

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To remain on the Australian Register of Therapeutic Goods (ARTG), a product or device must continue to comply with the relevant standards and conditions. Suppliers and manufacturers must therefore ensure that ongoing compliance processes are in place and must comply with mandatory reporting obligations, including to report reportable adverse events or reactions in respect of medical devices and registered medicines.

5.1 Medical devices

In order for a medical device to be registered on the Australian Register of Therapeutic Goods (ARTG) (i.e. approved for supply), the Therapeutic Goods Administration (TGA) must be satisfied that:

(a) there is appropriate evidence that the device can be used safely and effectively, including that the use of the medical device does not compromise health and safety, the design and construction of the medical device conforms to safety principles, the medical device is suitable for its intended purpose, long term safety requirements are met, the medical device is not adversely affected by transport or storage, and the benefits of the medical device outweigh any side effects (these being the 'essential principles') as well as additional design and construction principles which apply on a case by case basis. Different types of medical devices have different risk classifications and standards which must be met, and the Therapeutic Goods Administration (TGA) may also impose specific conditions in relation to particular medical devices, see http://www.tga.gov.au/industry/devices-argmd.htm;

(b) appropriate procedures are in place and implemented to ensure conformity with these principles and conditions on an ongoing basis; and

(c) once a medical device is included on the Australian Register of Therapeutic Goods (ARTG), sponsors and manufacturers have ongoing obligations, as set out in http://www.tga.gov.au/industry/devices-argmd.htm, including:

- to maintain conformity assessment evidence to be able to demonstrate that the medical device continues to meet the 'essential principles' and other conditions of inclusion on the Australian Register of Therapeutic Goods (ARTG) and to keep distribution records in relation to the medical device;
- to report to the Therapeutic Goods Administration (TGA) particular adverse events in relation to the medical device within certain timeframes, including overseas recalls in relation to medical devices from the same batch or production run supplied in Australia, and to otherwise provide the Therapeutic Goods Administration (TGA) with regular reports if required for that class of device;
- to recall medical devices which do not comply with relevant principles and conditions and inform the public. Other action may be taken by the sponsor (such as safety alerts) in relation to such medical devices; and

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- for manufacturers, to have in place a process to implement corrective measures, and to notify the Therapeutic Goods Administration (TGA) / sponsor in relation to defects information, including malfunctions or deterioration in performance, inadequacy of design or improper use which may lead to death or serious injury of a patient or user of the medical device, and to notify the Therapeutic Goods Administration (TGA) of substantial changes to the design or intended performance or quality management systems in relation to the medical device.

The Therapeutic Goods Administration (TGA) conducts ongoing monitoring of medical devices included on the Australian Register of Therapeutic Goods (ARTG), which may include reviewing and testing the medical device to ensure that it continues to comply with relevant standards and conditions and information provided when the device was included in the Australian Register of Therapeutic Goods (ARTG), inspections of records and documentation and audits and the TG Therapeutic Goods Administration (TGA) A may take corrective action in accordance with the Therapeutic Goods Act 1989 (Cth) and other relevant legislation.

5.2 Medicines

Broadly, there are two systems for inclusion of medicines on the Australian Register of Therapeutic Goods (ARTG):

- higher risk medicines which must be registered (eg prescription pharmaceuticals and certain higher risk over the counter medicines); and
- lower risk medicines which must be listed.

In an application for registration of a medicine, Australian sponsors are required to provide safety, quality and efficacy data, labelling and warning information and evidence that the products have been manufactured in accordance with Good Manufacturing Practice (GMP) standards. Applications in relation to prescription medicines must include quality data (eg composition, batch consistency, stability, sterility (if applicable) and impurity information), non-clinical data (eg pharmacology and toxicology data) and clinical data (eg results of clinical trials). Applications must generally also contain product information including with respect to the packaging, labels and any warnings relating to the product. The Therapeutic Goods Administration (TGA) may request additional data be provided, which the Australian sponsor must provide. Sponsors must also notify the Therapeutic Goods Administration (TGA) of additional information that arises post-submission, including any rejections of applications overseas, withdrawals of applications overseas, or significant regulatory actions which occur. Serious adverse reactions noted post-submission or which are inconsistent with the information reported in the dossier must be reported.

Listed medicines undergo a lower level of scrutiny by the Therapeutic Goods Administration (TGA) prior to listing. Applications for listing of an over the counter medicine must generally include quality data, information regarding the GMP status of the manufacturer, copies of labelling and packaging inserts, efficacy and safety information where relevant, and copies of product information and consumer medicine information documents where relevant.

Once a medicine is registered on the Australian Register of Therapeutic Goods (ARTG), the quality aspects of the product and the manufacturing systems cannot be changed without Therapeutic Goods Administration approval. Sponsors of prescription medicines must inform the Therapeutic Goods Administration (TGA) of adverse medicine reactions and safety alerts of which the sponsor becomes aware. Product recalls overseas that have relevance to the quality, safety and efficacy of the goods distributed in Australia must be immediately notified to the Therapeutic Goods Administration (TGA). Periodic Safety Update Reports must be provided annually for at least the first three years from the date of approval.

6. Whether Johnson & Johnson Medical Pty Limited (JJM) requires doctors to notify patients that they have a commercial relationship with Johnson & Johnson Medical Pty Limited (JJM).

6.1 The Johnson & Johnson Medical Pty Limited (JJM) International Health Care Business Integrity Guide.

As with other affiliate companies, Johnson & Johnson Medical Pty Limited (JJM) is required to comply with an internal International Health Care Business Integrity Guide (the Guide) that contains enterprise-wide standards for compliance with a number of legal regimes. It is intended to supplement national and international legislation and applicable industry codes.

The Guide sets out how Johnson & Johnson Medical Pty Limited (JJM) interacts with healthcare professionals (HCP) including the following principles:

- When engaging a HCP to act on behalf of the company, the services paid for by the Johnson & Johnson Medical Pty Limited (JJM) must fill a legitimate, documented business need and such services must be obtained from individuals who possess demonstrable special knowledge or capabilities to perform the services;
- These services must be properly documented in a written agreement, and that agreement must specify the complete compensation arrangements. Compensation paid must be fair market value for the services provided. Johnson & Johnson Medical Pty Limited (JJM) must document how fair market value was determined;

- Performance of services received must be documented and invoices from service providers must have sufficient detail to enable proper recordkeeping; and
- The agreement must contain a representation and warranty by the HCP that, in the event the HCP is or attains a position to influence purchasing decisions by a government entity or the HCP's employer, the HCP shall notify the purchase decision-maker of the HCP's financial relationship with Johnson & Johnson Medical Pty Limited (JJM) and otherwise comply with applicable requirements of local law. In such circumstances, the agreement will also permit Johnson & Johnson Medical Pty Limited (JJM) to terminate the agreement.

The Guide also sets out the requirements for arrangements under a Product Development Agreement or a licence for intellectual property rights. Again, such arrangements must be properly documented in a written contract that includes the complete compensation arrangements with the healthcare professional. In addition, if royalties are to be paid, the healthcare professional's contribution to the development of the product at issue must be documented. Further, the Guide requires that purchases by the applicable healthcare professional be excluded in the calculation of appropriate royalties to avoid the potential for improper influence.

The Guide does not require that Johnson & Johnson Medical Pty Limited (JJM) should ensure that healthcare professionals notify patients that they have a commercial relationship.

6.2 Professional standards of doctors and orthopaedic surgeons.

In addition to the requirements of the Guide, Johnson & Johnson Medical Pty Limited (JJM) expects the doctors and orthopaedic surgeons with whom it interacts to abide by their professional standards of conduct and ethics, including:

- The Australian Medical Council Good Medical Practice: A Code of Conduct for Doctors in Australia (the AMC Code) which applies to all doctors nationally registered within Australia. Section 8.11 sets out the requirements of a doctor to adhere to when a conflict of interest arises which may affect their care of a patient. [2]
- The Royal Australasian College of Surgeons (RACS) has a Code of Conduct (the RACS Code), which defines the standards of professional behaviour applicable to surgeons who are fellows of RACS. Section 8.1(4) specifies that surgeons will be honest and transparent with respect to any potential conflicts of interest.[3]

[2] The AMC Code can be found at: http://www.amc.org.au/images/Final_Code.pdf.
[3] The RACS Code can be found at: http://www.surgeons.org/media/30110/pos_2011_02_24_code_of_conduct_2011.pdf.

- The Australian Orthopaedic Association also has a Code of Conduct for members, which reflects appropriate professional standards and professional expectations for orthopaedic surgeons, above and beyond the requirements of the AMC Code, due to its unique discipline. Section 6.4 of the AOA Code requires that orthopaedic surgeons declare any conflicts of interest, in particular, financial relationships with prosthetic companies or hospitals and other corporate entities or persons.[4]

7. The protocols/thresholds regarding when Johnson & Johnson Medical Pty Limited will provide regulators in Australia and overseas with warnings about early signs of difficulty in a particular product or device.

Johnson & Johnson Medical Pty Limited (JJM) devises and manages internal product complaint handling procedures and conducts staff training programs on adverse reporting so that its internal complaint handling procedure is effectively followed. The complaint procedure involves the following steps:

- completing an online complaint form within 24 hours of receiving a product complaint (an orthopaedic planned revision is considered to be a complaint);
- assessing the complaint forms on a daily basis to confirm whether there is an associated adverse event (in which case, the health authority must be notified within the mandatory legislative timeframes);
- registering the product complaint onto an internal database;
- notifying the manufacturer (or their local department for marketing complaints) responsible for investigating the product complaint within two working days from the alert date; and
- notifying the manufacturers of all complaints reported to the Health Authority on a weekly basis.

The manufacturer will then initiate an inquiry to assist in the product investigation. All information obtained by Johnson & Johnson Medical Pty Limited (JJM) is incorporated into international information in relation to a particular product. Johnson & Johnson Medical Pty Limited (JJM) also devise annual complaint reports for higher risk products, including details of all complaints and adverse events both locally and worldwide.

[4] The AOA Code can be found at: http://www.aoa.org.au/Libraries/eCM_Files/CodeofConduct2010_240910_pdf.sflb.ashx

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Johnson & Johnson Medical Pty Limited (JJM) is also party to international quality agreements with manufacturers which reiterate the responsibility of Johnson & Johnson Medical Pty Limited (JJM) for mandatory medical device reporting to the Therapeutic Goods Administration (TGA). Reporting obligations are contained in the Therapeutic Goods Act 1989 (Cth) and the Therapeutic Goods (Medical Devices) Regulations 2002 (Cth). In accordance with these obligations, the Therapeutic Goods Administration (TGA) receives raw data relating to adverse events within the specified time period.

In addition, Johnson & Johnson Medical Pty Limited (JJM) provides the Therapeutic Goods Administration (TGA) with annual reports, which include local and worldwide complaint and adverse event data for higher risk products (ie class 2b and class 3). This data is required every year for the first three years of supply.

8. Further explanation of the statement contained on page 30 of Johnson & Johnson Medical Pty Limited's submission that "Australian standards are out of date"

The Australian regulatory framework for medical devices is substantially based on compliance with international consensus standards. The primary means of demonstration of compliance with safety regulations is by conducting testing to these standards. The range of standards is extensive. Many hundreds of separate standards are published which cover all aspects of regulation ranging from specific product standards to general areas of safety including electrical safety, sterility, toxicity, clinical trials and risk assessment.

The main standards bodies are The International Standards Organisation (ISO) and the International Electrotechnical Commission (IEC) and their European counterparts CEN and CENELEC respectively. These International and European bodies cooperate extensively and many documents are jointly developed under a framework known as the "Vienna Agreement".

Standards are formally referenced in regulation in Europe, in the USA, Japan, Canada, with most references being made to ISO or CEN standards.

Australia formally references a small subset of key standards, and routinely recognizes the bulk of international standards for medical devices used in other jurisdictions by means of acceptance of overseas regulatory approvals predicated on compliance with these standards.

Standards Australia republishes ISO and European standards pertinent to medical devices, making them available for direct purchase in Australia as "A.S." standards. Development of these standards is by expert working groups drawn from all of the member countries of the standards organisation, including Australia. In the early 2000s, Standards Australia withdrew its involvement in a number of key medical devices international standards development committees and ceased to maintain many of the Australian publications.

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The result has been that many critical standards published in Australia are now out of date versions of international standards and participation by Australian experts in international standards development has been curtailed.

The following table gives specific examples of Australian standards which support critical aspects of medical device safety which are very out of date and which are currently available for purchase from the commercial partner of Standards Australia SAI Global (online at http://infostore.saiglobal.com/http://infostore.saiglobal.com) .

Current International Standard	Current Australian Standard
Sterilisation	
ISO 11135-1:**2007** Sterilization of health care products - Ethylene oxide -- Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices	AS ISO 11135-2002 Medical devices - Validation and routine control of ethylene oxide sterilization (Identical to ISO 11135:**1994 – 13 years out of date**)
Electrical Safety	
IEC 60601-1:**2005** Ed. 3.0 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance	AS/NZS 3200.1.0:**1998** Medical electrical equipment - General requirements for safety - Parent Standard (Identical to IEC 60601-1:**1998 - 7 years out of date**)
Risk Assessment	
ISO 14971:**2007** Medical devices -- Application of risk management to medical devices	AS/NZS 4810.1:2000 Medical devices - Risk management - Application of risk analysis (Identical to ISO 14971-1:**1998 - 7 years out of date**)
Clinical Trials	
ISO 14155:**2011** Clinical investigation of medical devices for human subjects - Good clinical practice	AS ISO 14155.1-2004 Clinical investigations of medical devices for human subjects - General requirements (Identical to ISO 14155-1:**2003 - 8 years out of date**)

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Biological Safety

ISO 10993-1:**2009** Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process	AS ISO 10993.1-2002 Biological evaluation of medical devices - Evaluation and testing (Identical to ISO 10993-1:**1997 - 12 years out of date**)

Again, Johnson & Johnson Medical Pty Limited (JJM) appreciated the opportunity to make a submission to the Committee and to attend the hearing on 27th September.

Please do not hesitate to contact us on 02) 8875 3240 or via email should you require any further information.

Yours sincerely

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