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26 July 2011

Mr Stephen Palethorpe
Enquiries Secretary
Community Affairs Reference Committee
PO Box 6100
Parliament House
Canberra ACT 2600

Email: ec.sen@aph.gov.au

Dear Mr Palethorpe,

Re: The Industry Standards for Approval of Medical Devices

Thank you for your letter of 7th July 2011. I write on behalf of the Orthopaedic Surgeons and Board of Directors of SPORTSMED·SA Hospital and Orthopaedic Division. We are interested to contribute to and assist you with your enquiry. Specifically our interest and experience is with devices, implants and prostheses used in orthopaedic surgery.

Due to the relatively short time frame we are not able to respond to all of the terms of reference or in any great detail. However we feel that it is important to register our interest and preparedness to assist the enquiry at any point in the future if this was felt to be of benefit. We have prepared our response in two areas namely Arthroplasty Devices and Multiple Reused Devices.

Arthroplasty Devices

SPORTSMED·SA consider that the TGA is the appropriate authority to regulate medical devices. We understand that this is a major task given the number and variety of implants available. We also acknowledge that science and technology are delivering new devices to market which have the potential to enhance clinical outcomes and may offer a range of other benefits compared to existing devices in the Australian marketplace. However in the area of joint replacements failure rates may not be apparent until the implants have been in use for some years. Initial satisfactory assessment of an implant design, manufacture and clinical performance may not be sustained with time.

What is probably required is an orthopaedically agreed set of criteria that will automatically trigger a second tier TGA review of a TGA approved device. It may also be that this review may result in the withdrawal of that device from the market. National Joint Replacement Registry (NJRR) data is likely to be key in any review process for both triggering the second tier review and determining the outcome of any such review.

NJRR now has some years experience and a very comprehensive database on the failure and revision rates of arthroplasty prostheses used in Australia. Increasingly this data available through the NJRR annual report is being used to benchmark prosthesis performance against national averages and scientific literature reports. At SPORTSMED·SA we have used the data held by the NJRR to provide our Hospital and Clinic with our own Hospital and more recently

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surgeon specific annual reports in order to ensure that prostheses used at our institution perform within orthopaedically accepted failure rates. We know of no other hospital or institution that monitors surgeon and hospital specific outcomes of prostheses in this way. National hospital accreditation surveyors have commended SPORTSMED·SA on its comprehensive audit and Standards and Peer Review processes. However as stated we believe this practice is extremely limited at this point in time but does provide a potential mechanism for monitoring and reporting implant and device performance at the clinical coal face.

It is our view that the TGA should ultimately be responsible for issuing device warnings to the profession, industry groups and public but that the final decision about utilisation should be between doctor and patient after fully informed consent. In issuing any warnings we believe TGA should take into account all available information including NJRR data, published scientific literature and professional body industry opinion such as the AOA.

Multiple Reused Devices

Current TGA regulations have led to most manufacturers classifying medical devices as single use devices (SUD's). This has occurred despite any evidence of increased infection rates or increased device failure rates. This has been problematic and expensive for those who use many devices used as tools (not implants) in orthopaedic surgery. Devices / tools that can be cleaned and sterilised to current standards and are still fit for purpose i.e. still able to cut and shave can no longer be reused if the manufacturer labels the device an SUD. In this environment there is a strong financial incentive for a manufacturer to label all devices an SUD irrespective of whether it still is fit for purpose for subsequent use. As a consequence our utilisation and costs of consumable devices has increased 400% without any corresponding increase in revenue streams from private health funds or any decrease in measurable failure or complication rates. This whole area is in urgent need of review to enable a safe, cost effective and pragmatic outcome to prevail.

Thank you for your consideration of this brief report.

Yours sincerely,

Dr Andrew Saies
Orthopaedic Surgeon