Medical Technology Association of Australia

Ms Christine McDonald
Secretary
Senate Community Affairs References Committee
Parliament House
CANBERRA ACT 2600

Dear Ms McDonald

Reference: Proof Committee Hansard, Senate Community Affairs References Committee, Regulatory standards for the approval of medical devices – Tuesday 27 September 2011

At the subject committee meeting, the Medical Technology Association of Australia undertook to respond to two questions on notice. The answers to those questions are provided below.

Question 1, page 9: Senator Xenophon requested clarification of evidence provided by Dr Armitage regarding safeguards in place in France with respect to access to prostheses.

Answer to question 1: The evidence given by Dr Michael Armitage conflates two activities - the assessment of a medical device for safety and efficacy which is a regulatory function, and the determination of reimbursement, which is a price control mechanism.

France, as a member of the European Union, participates in the regulatory system that applies across the EU. This system is very closely aligned with the Australian system. A product may be introduced into the market once it receives regulatory approval.

The reimbursement system in France is also not dissimilar to the revised process in Australia for listing a medical device for reimbursement by the private health insurers. In France a product is listed with like products and allocated a uniform price. If a supplier seeks a premium over and above the uniform amount it must show clinical superiority of the product based on the 'expected benefit'.

There is no mechanism which per se limits the number of devices entering the French market. The difference is in the level of reimbursement based on establishing a claim to clinical superiority. This is similar to the arrangement which applies to grouped products listed on the Prostheses List in Australia. Any claim for a premium or uplift in benefit must be based on establishing evidence of increased clinical effectiveness and/or cost benefit.

Question 2, page 13: Senator Brown - Would doctors be able to send those (withdrawn) products back to the manufacturer for reimbursement?

Answer to Question 2: Orthopaedic joints are supplied to hospitals in a practice known as “consignment stock”, i.e. stock that is in the possession of the customer (the hospital), but is still owned by the supplier (the orthopaedic company). The hospital purchases the orthopaedic

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products only after the items have been implanted by the attending orthopaedic surgeon. If orthopaedic products are withdrawn from consignment stock held by a hospital, there will be no need for the supplier to provide a refund as the items will not have been used nor paid for. This is generally the case for implantable load bearing joints and applies to both private and public hospitals.

In the area of Sports Medicine implants and a variety of other prostheses (e.g. dental/oral & maxilla/hand), hospitals may purchase stock in advance. In the case of a recall or removal of a device for safety reasons, a company would usually offer a refund or the substitution of a comparable device.

Yours sincerely

Anne Trimmer
Chief Executive Officer