Medical Technology Association of Australia

Senate Standing Committee on Community Affairs

Inquiry into Private Health Insurance (National Joint Replacement Register Levy) Bill 2009

Submission by
Medical Technology Association of Australia

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1. Introduction

The Medical Technology Association of Australia (MTAA) represents the manufacturers, exporters, importers and distributors of medical technology products in Australia. Medical technologies are products used in the diagnosis, prevention, treatment and management of disease and disability. They include a wide range of implantable prostheses, including orthopaedic prostheses used in procedures for joint repair.

MTAA is concerned at the public health and cost implications of the proposed levy on suppliers of orthopaedic joints to meet the operating costs of the National Joint Replacement Registry. MTAA welcomes the opportunity to outline its concerns about the *Private Health Insurance (National Joint Replacement Register Levy) Bill 2009* to the Senate Standing Committee on Community Affairs.

2. Background – role of registries

Registries perform multiple functions. They can provide one set of data to inform post-market surveillance and clinical follow up. Some registries are established by individual companies when a new product is released onto the market to provide controlled clinical information on product performance. This is a device specific registry which assists the company and the regulator to address real life characteristics of a product.

Registries have been used by health authorities to track a particular user cohort to ensure that patients are readily identifiable as was the case with the breast implant register after early failures of implants in some patients.

Class registries collect data on all devices and procedures used in a specific class of surgery. The National Joint Replacement Registry (NJRR) is a class registry in that it collects information on close to 100 per cent of orthopaedic procedures in Australia. It is then able to track occurrences of revisions of the orthopaedic devices used in the original procedure. The information collected by the NJRR is able to identify a range of reasons for revision, including surgeon technique, hospital-related infection, patient compliance, and device performance.

NJRR is the first national comprehensive class register. The information collected by the NJRR is used for multiple purposes – to contribute to post market surveillance by the regulatory authority, Therapeutic Goods Administration (TGA), to monitor ongoing quality and safety of devices; to inform surgeons on clinical performance; to identify hospitals with a higher than expected infection rate; and to inform companies on product performance.

3. Issues of concern to MTAA

MTAA has long been a supporter of the value of well-designed and appropriate registries. Indeed, MTAA members committed funds to the pilot study for the establishment of the NJRR. However MTAA also believes that good public health policy which requires the active monitoring of the use and performance of products post-market should be a cost of the health system. Good outcomes, of both products and procedures, are in the interests of all Australians.

In the Explanatory Memorandum to the Bill, the Government has suggested that the monitoring of safety and quality of devices provides considerable benefit to the industry by improving consumer confidence in the safety and efficacy of joint replacement devices. The Government argues that any device showing a high failure rate can be identified quickly and removed from the market. Review by the NJRR is not so simple – cause of failure can be for reasons other than device failure which is why NJRR is beneficial to multiple stakeholders, including clinicians and hospitals. Indeed a well-designed registry should be able to inform multiple activities, from product redesign to clinical education. Removal from the market is an assessment made by TGA, after consideration of the evidence before it, including data from the NJRR and from the manufacturer and/or sponsor in the case of imported products.

The data available from the NJRR has also been used by the private health insurance industry to influence the level of reimbursement of comparator products listed on the Prostheses List.

The Explanatory Memorandum also states that the data produced by the Registry assists industry by informing development of new prostheses, allowing manufacturers to draw on reliable performance information for existing products and designs. This is certainly true. However in order to access this level of detailed information from the registry, a manufacturer also has to pay for the data. This fee would no doubt continue and is certainly not regarded by the NJRR as an operational cost.

The cost is a further impost which the current pricing process does not allow to be passed on by the supplier. It comes on top of a cost recovery fee imposed by the Department of Health and Ageing for the listing of a product on the Prostheses List (which includes implantable orthopaedic devices). These costs have added significant burden to suppliers at a time when the negotiation of reimbursement by the private health insurers for items listed on the Prostheses List has been aggressive in holding down any price increase. In the period between February 2006 and February 2009, the average minimum price of an item listed on the Prostheses List increased by a mere 1.4%, and declined by 8.0% when adjusted for inflation. Suppliers are not able to continue to absorb additional imposts.

While items listed on the Prostheses List are only those supplied to the private health system, suppliers would be left with no alternative but to increase prices in the public health system as a result of the levy for the NJRR.

MTAA is also concerned that the imposition of a levy for the operations of the NJRR will create a precedent in an environment where it is likely that there will be further registries in the future. Future registries are unlikely to be class registries like the NJRR but could include multiple elements extending beyond device monitoring. For example, a cardiac registry, in order to be effective and fully informative, would need to track not only cardiac devices, but also the range of cardiac interventional procedures, some not involving implantation of prostheses, and possibly also cardiac pharmaceuticals in order to fully compare the outcomes (and costs) of comparable treatments. It is both inequitable, and unrealistic, to look to device suppliers to meet the cost of such a registry.

MTAA has argued in its submission to the Government's Review of Health Technology Assessment that real world information needs to also include alternative surgical or pharmaceutical based treatment paths. Registries can contribute extensively to our understanding of comparative treatments and their outcomes. Technology sponsors should not have to incur the expense of collecting information on alternative therapies.

Indeed, questions of comparative or relative cost effectiveness should be the responsibility of the funders or professional colleges with clinical responsibility for a procedure. The funder is seeking information on more than one product and its costs and benefits compared with an alternative path. This type of information cannot be the responsibility of a single sponsor; rather it needs to be the responsibility of the funder seeking the answers.

MTAA also argued in its submission that by clearly aligning the cost of obtaining the information collected by a registry with the persons seeking it, there is an element of fiscal discipline. Failure to align incentives could result in a proliferation of registries and significant escalation of cost to the health sector. Ultimately, it is the funders (overwhelmingly the Federal Government) that will bear the costs of any increase in post market registries.

The Government has indicated that it will apportion the levy across the products listed on the NJRR with an individual product amount varying from $0 to $5000. MTAA's analysis of the orthopaedic products listed on the Prostheses List (and therefore the subject of surveillance by the NJRR):

- 47% of products have minimum benefits less than $1000
- 89% of products have minimum benefits less than $4000
- 99% of products have minimum benefits less than $8000.

This suggests that products will be attracting a significant, and disproportionate, individual levy to meet the projected Budget savings of $5 million over four years.

Page 2 of the Explanatory Memorandum cites joint replacements that receive benefits as high as $67,000 per product. While there are two products at this level of benefit, they are highly specialised custom made expandable joints used in paediatric surgery and have utilisation averaging one or two per year at most. The next most expensive orthopaedic implant is $26,000 while the average benefit for listed orthopaedic products is $1,732. In focusing on product listings alone, the Explanatory Memorandum fails to recognise the relevance of the extent of utilisation of products in both the private and public sector to establishing a fair, equitable and sustainable tax.

The use of cost recovery to underwrite registries has been approached in different ways globally. The Explanatory Memorandum shows no evidence that Government has explored the practicality and lessons learnt from other options but instead has settled on the most expedient solution. Government should be invited to detail its broader research to the Senate Community Affairs Legislation Committee.

The Department of Health and Ageing has not consulted with industry on this proposed tax and so MTAA has not had the opportunity to consider with the Department a more equitable solution.

4. Conclusion

MTAA urges the Senate Committee to consider the issues raised in this submission, and to recommend rejection of the *Private Health Insurance (National Joint Replacement Register Levy) Bill 2009.* While the sum sought to be saved to the health budget is insignificant in the context of the total budget, the imposition of the levy raises issues of concern for public health policy and for the future development of registries in the Australian healthcare system. The levy also raises issues of equity where one sector is looked to, to fund a service that is of benefit to many stakeholders not least of which is the healthcare system itself.