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October 1, 2021

RESPONSE TO CONSULTATION PAPER

Methodology for Determining the Benchmark Price for Prostheses in Australian Public Hospitals.

MicroPort CRM support the response submitted by the Medical Technology Association of Australia (MTAA) and that of the Cardiac Forum of the MTAA which comprises the five (5) Australian subsidiaries of the manufacturers of cardiac implantable electronic devices (CIEDs).

In addition I would like to make the following comments, whilst they may not be in response to the specific questions in the consultation paper, I believe are relevant in the broader medical device/prostheses market place.

MARKET PRICE

An alternative pathway to obtain more evenness in pricing and reimbursement between the public and private sectors in the Australian market place, would be to establish a national price across all states for medical devices. This would be the price paid by public hospitals, irrespective of volume and be the same quantum health insurers would be required to reimburse to their members. This would create a greater level of *equity across the health spectrum* and help to ensure patients receive the same level of health care no matter their location or insurance position. I understand that there are jurisdictional and inter governmental barriers to this, however if the goal is fairness of health care then these barriers needs to be navigated.

Implementation over a period of three years would see public prices gradually increase to and reimbursement levels reduce to, the national price. The government could create a transition fund partially financed by private insurance sector, and a governmental subsidy. The progressive reduction of the administrative price would lead ultimately to cancel out during the transition period. This would prevent any significant disruption in the market, clinicians would retain choice, consumers would benefit from lower insurance premiums from insurers as a result of lower reimbursement levels for devices and the industry would remain intact, which is far from guaranteed under the framework being promoted by the government.

Under the current framework, the proposed changes lead to a situation which is likely not sustainable with principles that are sub-optimal. In particular a strong reimbursement drop will lead to a removal of essential services (especially in CIED's and other active implantable devices) and evolution toward lower tier products

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including products with poor longevity and performance. This has been observed in other geographies around the world e.g. Nordic region.

First authorities need to understand that there is no "free" grab. Actions will have consequences and authorities who are more concerned with political consequences (perceived short-term wins) should be concerned first by quality of devices (including longevity) and quality of services. There are multiple experiences and learnings in many geographies.

A more stable approach would be a system similar to the French or the Japanese, where there is one single price set up by authorities and periodically revised, for both private and public sector. The price should include the price of the services. The information regarding the cost of services, in the Australian instance for CIED's has been communicated to government.

Underpinning this scenario above is the acknowledgement that the health system in Australia is a hybrid system, which aims to provide the best care possible. Hospitals treat both public and private patients, as do physicians many of who practice simultaneously in both public and private. In essence, what has allowed the Australian heath system to work well, by global comparison, is due in part to the synergy and cooperation across and within the system. The public needs a strong private and vice versa. To look at one in isolation is fraught and will lead to erosion of services overall. The result will be increased hospitalisations and of course increase costs for both public and private patients.

A legitimate and unavoidable difference between current public and private prostheses pricing for CIED's is the necessity of lifetime technical support services (Refer to MTAA and Cardiac Forum submissions). Historically services were an important consideration in reimbursement levels. A precedent has been set.
To separate the supply of a CIED and the required services would be detrimental to patient care, creating consequences, otherwise avoided if they were to remain together i.e. a package of device and lifetime services. Separating these would not ensure the provision of essential and highly technical services. Physicians and or hospitals may be forced to cease engaging in these procedures i.e. stop implanting CIED's due to patient safety concerns. This has happened in other markets where private hospitals have not been able to guarantee the specific and high levels of services required.

HIDDEN COSTS

Other costs for consumables and accessories which in practice have been provided a no cost to hospitals for the implantation of CIED's will need to be accounted (paid for) should reimbursement levels be reduced by the amount indicated by government. Examples include introducers, catheters, guide wires, caps, plugs and cables. These have not insignificant manufacturing, quality and regulatory costs, which have been included in a "package" approach by many manufacturers. However these will be specifically be charged for manufacturers in the face of unsustainable reimbursement cuts. The costs will flow through both public and

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private hospitals. In addition, costs for the supply of capital equipment must be included. In the CIED field these include programmers and patient specific analysers both of which are important in the checking of the patients device status at the time of implantation and at subsequent checks for the life of the device. Again, significant costs absorbed by industry with each software upgrade requiring regulatory approval and hence costs, on top of the initial market entry costs.

Having worked across many disciplines of the medical device industry for thirty years, I am aware that this is not a situation unique to the CIED space.

I understand the intent and direction the government is wishing to move toward. However, I am deeply fearful that after years of ongoing reimbursement cuts *(CIED have had greater than 35% reductions on the past 4 years)* that this will be a cut too deep and rash, unnecessarily compromising the healthcare system with catastrophic consequences in a number of areas.

I am of course available for any further comment or clarification on the contents of my response.

Sincerely

BRIAN CONNORS

Vice President

MicroPort CRM Pty Ltd.