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Submission to the Productivity Commission re Government Cost Recovery

In accordance with your call for submissions on cost recovery by Commonwealth Government regulatory (and other) agencies, Cochlear Limited is pleased to address the following key issue:

Current 100% cost recovery practices within the Therapeutic Goods Administration (TGA), are a matter of key concern and a disincentive to healthcare delivery and industry development.

Cochlear Limited is a publicly listed Australian company designing, manufacturing and marketing medical implants for the purpose of restoring hearing percept for the profoundly and severely hearing impaired. More than 90% of our products are exported world wide and are subject to medical device regulations in Australia, USA, Canada, European Commission, Japan and others.

The regulatory agencies have different approaches to the fees and charges applied to industry, related to market approval and ongoing access to their regulated markets, ranging from no charges in the US to a 100% cost recovery policy applied by the Government to the TGA in Australia. Because of these policy differences, and especially the 100% cost recovery policy which TGA must enforce, the regulatory fees and charges in Australia far exceeds those in other regulated economies.

The table below illustrates the fees and charges for a full submission of a high risk medical device since June 1998 showing the difference between the agencies.

Country	Regulatory Agency	Fees $A June 1998	Fees $A Aug 1998	Fees $A May 2000	Relative market size[1]	Recovery Relativity factor[2]
Australia	TGA	$41,000	$59,000	$76,000	1%	760
Canada	TPP	$15,800	$15,800	$19,800	3%	66
Europe	TUV	$8,500	$8,500	$12,800	26%	4.1
USA	FDA	Nil	Nil	Nil	41%	0
Japan	MHW	$8,700	$8,700	$11,100	18%	6.2

1. Medical device market estimates made by Health Industry Manufacturers Association USA in 1993.
2. A relativity factor based on the regulatory fees divided by the size of the markets as an indicator of degree of difficulty to recoup regulatory expenses.

The table also shows the relative market sizes and therefore demonstrates the much higher entry barrier of a high risk medical device in Australia compared to the other countries.

Thus the impact of 100% cost recovery policy is to make market entry in Australia too expensive for many companies. Companies do not introduce new products to the Australian market where it is apparent that high up-front costs for evaluation and entry onto the Australian Register of Therapeutic Goods (ARTG) cannot be recovered in the often short market-life of the product. Even more concerning is the discouragement to potential start up companies which could greatly benefit from having a lower cost access to the local Australian market to build their business prior to overseas expansion.

It should also be noted that there is little net gain for the Government in the application of the 100% cost recovery policy. Importers and manufacturers increase the price of medical equipment to recover these costs. The higher prices ripple down the supply chain to the public, to be reimbursed, in many instances, via Medicare. The Government will, therefore, indirectly bear the brunt of its own cost recovery policy.

In summary there 100% cost recovery policy is possibly near neutral for the Government while the consumers, practitioners of quality health care and industry lose.

The above points are serious and justify a review and a change in the 100% cost recovery policy for the TGA. This is especially opportune now that the TGA regulatory framework is being changed to a model in line the Global Harmonization Task Force on Medical Device regulations, a task force which membership is the USA, Canada, Japan, European Commission and Japan.

Cochlear Limited expresses thanks for the opportunity to lodge this submission and remains ready to address any questions of detail.

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