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AWIN SERVICES

*ProdComm250501*

Friday, 25 May 2001

The Assistant Commissioner
Cost Recovery Inquiry
Productivity Commission
Locked Bag 2
Collins Street East
Melbourne VIC 8003

Dear Sir/Madam

**PRODUCTIVITY COMMISSION**
**COST RECOVERY DRAFT REPORT**

AWIN Services made a previous submission (No. 20) entitled THERAPEUTIC DEVICE PRODUCTS. We are concerned that the draft report frequently discusses therapeutic goods solely in terms of medicines (drugs), without differentiation. Therapeutic goods are regulated separately by the TGA as prescription medicines, complementary medicines and devices (which includes diagnostics). The markets and users for these vary enormously, and we would request that differentiation be provided. Medical devices range from complex high-risk goods such as heart vales and implantable defibrillators to cotton-wool balls and cotton buds. Products often have relatively short life spans, making time to profitability for companies often very limited. We believe this differentiation has not been addressed.

For device products, the beneficiary is also less clear. The bulk of the goods, including most high risk goods, are supplied to health care providers, while a lesser quantity of lower risk goods, such as cotton-wool balls and dressing strips are supplied direct to the consumer, in this case, clearly the user. The "beneficiary" or "regulated" alternatives become confused, especially when, for device products, the user is the healthcare facility or healthcare provider in the majority of cases, bearing in mind many items, such as equipment, are reusable, benefiting a vast range of patients over several years. Many consumers benefit by providing the health care provider with a "tool" to allow him/her to provide the patient with a service. Other than those limited products provided through retail, the customer is either the state government, funding hospitals, the Commonwealth Government (Medicare) or private health funds through prosthesis benefit Scheme. Passing on additional costs to such groups is extremely difficult for many suppliers, particularly in the less than high-risk product area, yet these are the beneficiaries under the various definitions provided in this document.

Most importantly, we would ask that you make corrections under :

**Cost recovery Other Jurisdictions G.7 Pages G13-G15**

We would refer you again to our submission entitled Therapeutic Device Products:

- USA does not have cost recovery programs for pre-market evaluation of Devices. Your claim that the quotes in MIAA Sub 12 and AWIN sub.20 are incorrect, needs correcting. The AWIN submission, and indeed the MIAA submission both refer to devices, and your data quoted under USA refers solely to medicines (drugs), food or services.

- Canada. The costs quoted here again are misleading. Until the year quoted, Canada had not regulated devices at all. The commencement of device regulation lead to a requirements for all devices supplied previously to be evaluated, creating an enormous backlog, however the figures quoted again are for medications, not devices, and bear little relation to the costs imposed on device suppliers.

- United Kingdom. The costs quoted are solely for medicines (drugs), and include no device figures at all.

Thank you for this opportunity to review the document.

Yours faithfully

Heather Winslade
Director