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AWIN SERVICES

hw/pc/1100

5 November 2000

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

Dear Sir/Madam

THERAPEUTIC DEVICE PRODUCTS

You have received input from Medical Industry Association of Australia (MIAA) as the peak body in this area, however I additionally consult with smaller often entrepreneurial non-member companies seeking to enter this market, and would like to comment at that level.

In this area, the term "companies" most typically means a company comprising one to four people. In two cases, the companies were small companies currently trading in different fields, where the technology used was seen to have useful application to be extended to the therapeutic device market.

At the time that such companies contact me they have either seen a product overseas, which they have estimated to have marketable value in Australia, or commenced the development of a product locally. Most are unaware until this time that there are Fees and Charges to 100% cost recovery involved with the regulator, although CSIRO charges have been seen as potential concerns.

Where that product falls into the group of products requiring pre-market evaluation, problems arise. The cost of meeting the local requirements currently is significantly higher than equivalent costs overseas, and indeed in the USA, the second largest single market after the EU, the regulator has no fees or charges. You may elect to have your product reviewed by an external approved body, which speeds the evaluation time with FDA significantly, but this is your own commercial decision. In Australia there in no fee-for service, and the money must be paid before the evaluation commences, with no contractual time frame to approval. For start-up companies seeking venture capital or other finance, this causes concerns for the financial controllers, especially when the period probably overlaps a financial year. It also significantly extends the period before the company and/or product is likely to be profitable. Following pressure from MIAA, a facility for companies to claim "hardship" and stagger the payments was made, however this does not appear in the Therapeutic Goods Act (Charges) Regulations.

For Australian companies wanting to manufacture, the most logical move, as seen by the financiers, is to bypass Australia and go direct to market in either the USA and/or EU. The USA would want the manufacturer to be approved, so there would be the cost of an audit, however this would be the only cost

to the regulator. For the EU, there would be the costs paid to a European-based Notified Body, however many now visit Australia regularly to see clients, and these costs are seen as acceptable in light of the available market size. The project becomes a commercial decision, complete with known contracted time frames.

Under the Australian/EC MRA, the TGA can now act as a Conformity Assessment Body, the term used for non-European based bodies undertaking the responsibilities of a Notified Body. Companies have concerns, however, about using the regulator in such a role, which is handled in the EU as a commercial role. The concerns cover several issues; the lack of local specific expertise in many areas; the future use of the data (will the data have normal commercial protection, or will it fall under government-regulated release), and finally will commercial time frames be met? The decision to allow the regulator to take on this role is seen by these companies as non-commercially oriented and anti-competitive.

In one case that I know of, this has actually sent the manufacturing offshore, and thus lost to Australia. In a second, where there is an existing small business, the business cost to improve the facility to meet both Australian and international requirements has put the decision to proceed on hold pending further evaluation because of the high cost of the Australian regulator of market entry, including manufacturing licensing, to a small market.

For a manufacturer, the limited availability of microbiological laboratories for testing becomes an additional issue. Manufacturers can only use laboratories that are TGA-licensed. All laboratories are required to be NATA-accredited, and many do not want the additional expense of having to pay two government authorities. This reduces the competitive availability of approved laboratories for manufacturers.

In summary, local regulatory costs are seen as prohibitive to market entry for new companies, particularly in a relatively small market, with a resultant potential limitation of competition.

Thank you for this opportunity to present these views.

Yours faithfully

Heather Winslade
Director