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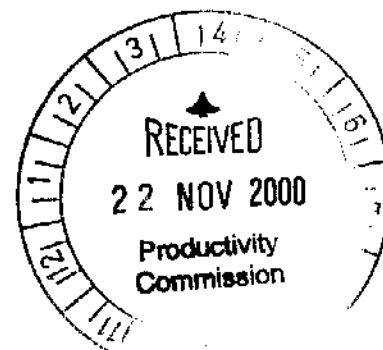
L A W Y E R S

23 February 2000

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Mr Brian Vale
Executive Officer
Medical Industry Association of Australia
126 Grenville Street
CHATSWOOD NSW 2067

Our reference
TB/MED11080-3376101



Dear Sir


TGA CHARGES

You seek our advice in relation to charges imposed by the Commonwealth in relation to therapeutic goods regulation.

Put broadly, the charges concerned are for evaluation of drugs and devices (which are provided for in the Therapeutic Goods Regulations) and for maintaining an item on the Therapeutic Goods Register (which are provided for in the Therapeutic Goods (Charges) Regulations). We have sought the advice of Alan Robertson SC on the question and passed to you a copy of his advice.

The position can be summarised as follows:

- 1 Counsel concludes that therapeutic goods "charges appear clearly to be such as to constitute taxation rather than fees for services".
- 2 At least where it could be established that an evaluation fee (which is imposed under the Therapeutic Goods Act and Therapeutic Goods Regulations) "was not reasonably or rationally related to the service provided to" the particular applicant, that fee would not be properly imposed. That is because the Therapeutic Goods Act expressly does not authorise the imposition of taxation.
- 3 The Therapeutic Goods (Charges) Act is a law with respect to taxation and authorises the imposition of taxation on the industry.
- 4 Counsel notes that at the time the Therapeutic Goods (Charges) Act 1989 was introduced to and considered by the Parliament there was a substantial re-arrangement of Commonwealth legislation imposing


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23 February 2000

Page 2

Medical Industry Association of Australia

TGA CHARGES

charges in light of the decision of the High Court in *Air Caledonie International*. It was usual practice at that time for the Government in its second reading speeches or explanatory memoranda to refer to that decision or to otherwise indicate its intention to have the Parliament authorise the imposition of taxation.

- 5 We have perused the explanatory memoranda and Parliamentary debates in relation to the Therapeutic Goods (Charges) Act. At no point did the Government of the day disclose to the Parliament that the Therapeutic Goods (Charges) Act would authorise the imposition of taxation on the industry. The Act itself avoids use of the term "taxation" and rather refers to "the charges".
- 6 We understand that regulations under the Therapeutic Goods (Charges) Act are made on the recommendation of the Department of Health without consultation with the Treasury. We note that under the Administrative Arrangements Orders the Treasury is responsible for taxation. We do not know whether it is in accordance with good administrative practice for line Departments to settle the details of taxation without consultation with the Treasury.
- 7 We understand that the evaluation charges made under the Therapeutic Goods Act are to be increased shortly by up to 300 percent in order to enable the Government to achieve its stated policy of 100 percent recovery of the costs of administering the TGA. In our view, such an increase would render those charges taxation (see paragraph 2 above). The Regulations under which they are principally imposed would be invalid (see paragraph 2 above).
- 8 It would be in accordance with good Parliamentary practice for the Parliament in considering amendments made to the regulations under the Therapeutic Goods Act and Therapeutic Goods (Charges) Act to consider them as a package imposing taxation on the industry.

Yours faithfully

CORRS CHAMBERS WESTGARTH



Tom Brennan
Partner