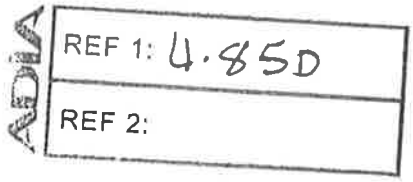
Ref: 4.8.5d — 16 August 2011



Mr Philip Weickhardt
Presiding Commissioner
Inquiry Into The Australian Retail Industry
Productivity Commission
GPO Box 1428
CANBERRA ACT 2601

Dear Mr Weickhardt

RE: Draft Report - Economic Structure & Performance of the Australian Retail Industry

The Australian Dental Industry Association (ADIA) has reviewed the draft report reviewing the economic structure and performance of the Australian retail industry and takes this opportunity to comment.

ADIA does not believe that the draft report adequately addresses the demonstrated risks to public health associated with the importation of medical devices (*e.g.* dental product) via the internet by healthcare professionals and the subsequent supply of this product to patients. In this respect the Commission's failing places at genuine risk consumers and patients exposed to dental product purchased online and beyond protections afforded by the *Therapeutic Goods Act (Cth) 1989.* As the report is in draft form, there is the opportunity for the Commission to fully consider the matter and ADIA commends this course of action to you.

In the limited way that the draft report has addressed the matter the Commission has misrepresented the regulatory arrangements that pertain to the supply of therapeutic product. In Section 4.13 the draft report states:

> *Another domain of regulatory activity is in relation to therapeutic goods. Although it is possible to obtain legitimate, TGA-approved therapeutic goods from reputable Australian online providers, it is possible that therapeutic goods available for purchase from international websites are not identical to the products available for supply in Australia and therefore may not be the product regulated by the TGA. As such, they may not meet the same standards of quality safety or efficacy of products legitimately available in Australia.*

This section seems to imply that medical devices appearing on the Australian Register of Therapeutic Goods (ARTG) can be purchased online and supplied so long as they are "identical to the products available for supply in Australia". Under existing law this not the case as a healthcare professional that purchases medical devices (that are identical in all respects to products with existing ARTG entries) online with the intent to use them is required to separately arrange for the products' entry on the ARTG and meet the attendant statutory obligations.

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ADIA believes that it is prudent that the report highlight the fact that the current medical device regulatory framework was designed in the last two decades of the twentieth century and is becoming increasingly irrelevant in the twenty-first century. It is possible to purchase medical devices from overseas sources via the internet, a possibility simply not envisaged in the 1980s and early 1990s when the legislation was initially drafted and the supporting regulatory framework put into place. The outcome is that many high risk medical devices such as autoclaves, tooth filling materials and even bone grafting materials can be imported via the internet with no safeguards as to their fitness for use.

We look forward to further supporting the work of the Commission in satisfactorily addressing this issue.

Yours faithfully

Troy R Williams AFAIM MAICD
Executive Officer