Australian Government
Productivity Commission

REVIEW OF AUSTRALIAN GOVERNMENT'S RELATIONSHIP WITH STANDARDS AUSTRALIA LIMITED AND THE NATIONAL ASSOCIATION OF TESTING AUTHORITIES, AUSTRALIA

I am a Professor in the School of Dental Science, Faculty of Medicine, Dentistry and Health Sciences, University of Melbourne. From 1984-1990 I was employed at the NATA-Registered Australian Dental Standards Laboratory, Commonwealth Department of Health, which is now part of the Therapeutic Goods Administration (TGA). I have been involved in dental standardization activities both domestically and internationally since 1984, and have led the Australian delegation to the International Organization for Standardization (ISO) Technical Committee 106 (Dentistry) since 1988. I am Chairman of the Australian Dental Association Inc (ADA Inc) Therapeutics, Instruments, Materials and Equipment Committee, which has a strong interest in dental standards. I am also an associate member of the Medical Device Evaluation Committee and of the Joint Interim Expert Advisory Committee on Standards, and a member of the Health Standard Sector Board of Standards Australia (SA). This submission represents my personal views and does not necessarily represent those of the University of Melbourne or the Australian Dental Association Inc.

Since my main experience is with standardization of the dental products, both domestically and internationally, my submission will be restricted mainly but not exclusively to this area. I am not qualified to comment on NATA issues.

I therefore wish to make submission in the two of the areas identified by the Commission:

a) *the efficiency and effectiveness of standards setting* …
I am unable to make substantial informed comment on this aspect, as I have not been involved in a dental standard-setting committee for some time. However, my perception is that the process is now reasonably efficient compared to, say, 5 years ago.

The only other comment I would make concerns effectiveness. Based again on perception rather than hard data, I question whether enough accountability exists in SA's standards development system to justify modification of ISO/IEC standards and republishing as Australian Standards. Without strong justification, there may be issues regarding Australia's World Trade Organization agreements.

b) *the appropriate role for the Australian Government in relation to standard setting* …
Australia has had a long history of standardization for dental products; by the 1980s there were over 50 Australian dental standards, which was more than any country except the USA and Japan. However, a reduction in the resources which Standards Australia committed to dentistry in the early 1990s, together with more emphasis on internationalization, has resulted in the withdrawal of all Australian domestic dental standards as corresponding international standards have been published.

For approximately the last 10 years, an Australian delegation has attended the meeting of ISO/TC106 (Dentistry). ISO dental standards are commonly republished as European (EN) standards, which have been collated into common product groups, and each resulting standard has

been republished as an Australian standard. These standards* are now used by the TGA as one option to legislate the supply of dental products.

Since most dental products are imported, compliance with ISO standards provides the most efficient and logical means of ensuring quality and safety, provided that TGA does not impose additional unique requirements. (Australia represents a very small part of the global dental market, and the imposition of unique product requirements which need specific changes to a product may compromise supply in Australia.) It is thus essential that Australia participates in the development of ISO dental standards, which requires attendance at TC106 in order at fulfil its obligations as a 'P' member. Australia currently has five delegates to TC106, and funding to attend meetings is provided partly by Standards Australia for four delegates, with the balance from ADA Inc. One delegate, the director of a dental industry company, is self-funded. Employee support by continuance of salaries is provided for four delegates; one is retired. The number of Australian delegates is not adequate to attend the required number of TC106 Sub-committee and Working Group meetings, since several take place concurrently; Japan, for example, regularly has over 50 delegates. The Australian delegation needs to be at least 10, but this raises funding issues. Compliance of dental products with international standards ultimately benefits the community's dental health, and thus is in the national interest; the required level of funding to attend ISO/TC106 should be provided by government and administrated by SA.

Several Australian standards which are non-dental, eg, sterilization, wiring of medical treatment areas, radiography equipment, also have an impact on dental practice. Many Australian standards committees therefore have dental representation. As identified in the Commission's Issues Paper, representation is voluntary and unpaid. This has implications for 'end user' participation, i.e., dentists, since the majority of dentists is self-employed and time away from practice results in a loss of income. In contrast, committee members who are from industry are predominantly salaried, although they do depend on the goodwill of their employers to attend meetings. For both groups, travel costs can also be an obstacle, and for the reasons given above, government funds should be available for this purpose.

c) Other issues

Several Australian standards are now called up in legislation at the state level for mandatory compliance in dental practice. Some of these standards have been developed by SA Committees with substantial input from members of ADA Inc. However, for copyright reasons, members of ADA Inc are required to purchase such standards, and it appears that extracts on the ADA Inc website are also prohibited by copyright. It seems inequitable that ADA Inc members have made their intellectual property available to SA at some personal cost, and then have to buy it back. The Commission should give consideration to this issue.

[signed]

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* AS EN 1640-2002 Dentistry - Medical devices for dentistry – Equipment; AS EN 1641-2002 Dentistry - Medical devices for dentistry - Materials; AS EN 1642-2002 Dentistry - Medical devices for dentistry - Dental implants