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Reforms in the Medical Devices Regulatory Framework Discussion Paper

The Australian Dental Association Inc. (ADA) writes to you today with reference to the Department of Health and Ageing, Therapeutic Goods Administration (TGA), Reforms in the Medical Devices Regulatory Framework Discussion Paper.

About the Australian Dental Association Inc. (ADA)

The Australian Dental Association Inc. (ADA) is the peak national professional body representing about 12,000 registered dentists working in both the public and private sectors. Approximately 95% of registered dentists are members of the ADA.

The primary objectives of the ADA are:

- to encourage the improvement of the oral and general health of the public and to advance and promote the ethics, art and science of dentistry and
- to support members of the Association in enhancing their ability to provide safe, high quality professional oral healthcare.

Background

The Report of the Review of Health Technology Assessment (HTA) in Australia (HTA Review), released by the Minister for Health and Ageing, the Hon. Nicola Roxon, and the then Minister for Finance and Deregulation, the Hon. Lindsay Tanner, on 27 February 2010, made a series of 16 recommendations aimed at setting new directions for HTA in Australia to support better healthcare for all Australians, and to reduce unnecessary regulatory burdens on the sector while providing timely access to new and improved technologies and treatment modalities. The Government agreed to 13 of the 16 recommendations. Three recommendations which relate to post-market surveillance are subject to further consideration by Government due to the cost implications involved in their implementation.

A number of the recommendations had a direct impact on the TGA, its interaction with other HTA agencies, and improved post-market programs to better inform pre-market regulatory decision making. Recommendation 8, one of the Government agreed recommendations, focuses on the role of the TGA in ensuring medical devices supplied to the Australian market are manufactured under appropriate quality controls, are safe to use and efficacious in their application.

Recommendation 8

That the TGA in the context of international harmonisation:

Continue its role as the independent national regulator solely responsible for assessing the safety, quality and efficacy of therapeutic goods for entry on to the ARTG and marketing in Australia;

Respond to the issues raised in consultations regarding third party conformity assessment by July 2010, with a view to implementing changes agreed by Government by 2011;

Increase the rigour of assessment of higher risk medical devices by 2011, to ensure an appropriate level of evidential review is undertaken to ensure safety, quality and efficacy of these devices prior to entry on the ARTG and to provide a sound evidence basis for Commonwealth HTA processes; and

Develop protocols for information sharing with other HTA agencies through the Single Entry Point (SEP), subject to commercial-in-confidence constraints on the outcomes of its safety assessments.

Comments

The ADA wishes to indicate its strong support for the Australian Dental Industry Association's (ADIA) submission on this paper.

The ADA believes that the major impact of the proposed changes to regulations affecting the supply of therapeutic goods to the Australian market will have a direct impact on the dental industry. Such impact will be to significantly increase the regulatory burden and therefore the costs of dental products supplied in Australia. These costs will inevitably be passed on to dentists and other oral healthcare providers (e.g., dental prosthetists) who purchase dental products, and thus ultimately on to dental patients.

Devices Regulatory Reform Proposals

Please note that these recommendations correspond directly with the advice provided to you by the ADIA.

- Proposal 1 – Reclassification of Joint Replacement Implants

A new classification rule is added to Schedule 2 of the medical device Regulations to reclassify all hip, knee and shoulder joint replacement implants from Class IIb to Class III medical devices.

This proposal is not relevant to the dental profession and therefore the ADA is not in a position to make comment.

- Proposal 2A – Use of third party assessment bodies for Australian manufacturers

That Subregulation 4.1(1) is removed from the medical device Regulations, so as to no longer require Australian medical device manufacturers to hold TGA conformity assessment certification.

Advice provided to the ADA suggests that this change will have minimal impact on the Australian dental industry and therefore no comment is provided.

- 2B(i) – Devices requiring a TGA Conformity Assessment Certificate to be issued

Subregulation 4.1(2) of the medical device Regulations be amended to require a TGA conformity assessment certificate to also be issued for all Class III and AIMD implantable medical devices.

This change will have minimal impact on the Australian dental profession and thus the Association is not in a position to make comment.

- 2B(ii) – Applications to be selected for auditing

Applications to be selected for auditing Regulation 5.3 of the medical device Regulations be amended to require applications for all Class IIb implantable devices to also be selected for an application audit prior to inclusion in the ARTG.

This proposal significantly increases the regulatory burden and costs of introducing new implantable devices to the Australian market and this is likely to have a negative impact on access to dental implants. The proposal is therefore not supported.

- 2C(i) – Confidence building for EU Notified Bodies designated under the MRA

That the TGA commence discussions with the EC over a program of confidence building with the designated Notified Bodies under the MRA, which might include sharing of product assessments and observed audits of medical device manufacturers.

The need to increase the confidence that the TGA has in assessing bodies is both understood and agreed, with ADA supporting the TGA's decision to state the process of undertaking confidence building.

The ADA agrees with ADIA that the one qualification is that this process should be conducted only once a cost-benefit study has been undertaken and also that proper project management principles are in place so that the TGA's financial commitment is not an open-ended one.

- 2C(ii) – Recognising Australian third party assessment bodies

That further consultation be undertaken to investigate the development of a system whereby Australian based assessment bodies can be designated to issue conformity assessment certificates to Australian manufacturers.

This reform is welcomed as it will increase competition and choice for Australian manufacturers seeking the services of an assessment body.

- 3(i) – Amending the way a kind of device is included on the ARTG

Amend the way in which a kind of device is included on the ARTG.

The ADA concurs with ADIA in that a preferred alternative may be to simply list the 'product name' on the ARTG entry for a medical device. This will allow the public, healthcare professionals and the TGA to link a particular device to an ARTG entry without imposing a significant additional compliance burden on the dental industry by having to unnecessarily include updates for minor changes to a model.

Also the proposed time frame to update entries on the ARTG, this being twelve months, is too tight and will significantly increase costs to industry to comply with this change. There are doubts that a sponsor of imported product could comply at all in this time frame. It is proposed that a two-year time frame be used.

- 3(ii) – Enhancing the identification of approved devices

Enhance the ability to identify devices that have been approved by the TGA for supply in Australia.

Again, in proposal 3(ii), the TGA has not demonstrated a clear demand from either healthcare practitioners or consumers for this change. There is a need to subject this proposed change to a Regulatory Impact Statement (RIS) and undertake a cost-benefit analysis which properly measures the business compliance costs. Notwithstanding this, the following comments are made:

The TGA needs to clearly define what its intent is – on the device, labelling, packaging or instructions. The proposal is problematic for a device manufactured overseas as it is likely to require special production runs of product and/or packaging for product intended for the Australian market. This will significantly increase costs in the Australian healthcare sector, particularly given the proposals to introduce the changes over a relatively short time frame.

The TGA has stated that a key reason for the change is to rectify a situation where "healthcare providers and consumers cannot identify whether a device has been assessed by the TGA and is able to be supplied in Australia". As stated by the ADIA, the TGA has largely addressed this with proposals to improve data on ARTG entries including listing 'models' on the ARTG, something equally achieved by adopting ADIA's suggestion of including product names on the ARTG. A consumer or healthcare professional wishing to verify that their product appears on the ARTG need only know the product name and search for it on the ARTG.

- Proposal 4 – Publication of device product information on the TGA Website

Publication of device product information on the TGA Website.

The ADA supports transparency. However, the proposals put forward will considerably increase costs to patients and oral healthcare professionals, particularly if extended to lower-risk therapeutic devices. The ADA, like the ADIA, supports a scheme for higher-risk classification devices such as Class III and AIMD. Similarly, the ADA does not support a scheme of this nature for lower-risk devices.

With respect to the Australian dental industry, a great deal of the information will be produced overseas as approximately 98% of product is imported. The inclusion of such a scheme will significantly increase costs as the information is reviewed, edited, subjected to legal checks and then approved for publication. For lower-risk products the compliance costs represent an excessive burden for business which will escalate healthcare costs in Australia.

Thank you for the opportunity to comment on this important area.

I look forward to your response.

Yours sincerely

Dr F. Shane Fryer

Federal President