Ref: 11.11.15M — 6 February 2017

Director
Business Improvement & Support Section
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606

Dear Sir / Madam

RE: TGA Consultation – Designation of Australian Conformity Assessment Bodies

As the peak business organisation representing manufacturers and suppliers of dental products, the Australian Dental Industry Association (ADIA), takes this opportunity to comment on the proposed implementation pathway for the Therapeutic Goods Administration (TGA) to designate Australian conformity assessment bodies for medical devices.

It is understood that these reforms stem from recommendations derived from the expert review of medicines and medical device regulation, specifically recommendations fifteen and sixteen which were accepted by the Australian Government. ADIA is supportive of this course of action and commends the TGA for its demonstrated commitment to working with the dental industry, and the medical devices sector more generally, to review options available to the Australian Government to implement those recommendations. ADIA appreciates the opportunity to have been involved in those recommendations.

An independent economic analysis commissioned by ADIA indicates that the Australian market for dental products is $1.4 billion annually. The red tape associated with manufacturing and supplying dental products continues to place an unnecessary cost burden on businesses in this sector and it is in this context that ADIA welcomes the broad direction of the reforms. The paper released by the TGA has raised several issues and ADIA, having consulted with its membership, provides this response to those issues.

Existing Framework Preservation –

It is understood that the TGA plans to retain several aspects of the existing regulatory approval including the use of Existing Principles and the attendant conformity assessment procedures. This approach is supported.

ADIA is supportive of arrangements that will ensure that mandatory audit requirements will not apply for inclusion of a kind of medical device on the Australian Register of Therapeutic Goods (ARTG) where certification is issued by Australian conformity assessment bodies. This is consistent with the requirements that presently pertain to

certification issued by the TGA. Consistent with previous advice tendered to the TGA, ADIA believes that there needs to be clear and consistent criteria as to how applications are selected for discretionary audits – the current decision making framework is ambiguous.

Partial Designation —

ADIA is supportive of a process that allows Australian conformity assessment bodies to achieve partial designation for certain classification of medical devices (*e.g.* Class IIB and lower). This is particularly relevant to the dental industry where the majority of products are of a relatively low-risk nature. ADIA is therefore supportive of a TGA designated Australian conformity assessment body to undertake certification for only some types and / or classes of medical devices.

Existing Certification Source Consideration —

The suggestion that for conformity assessment applications submitted to an Australian conformity assessment body, where the manufacturer already holds conformity assessment certification from a European notified body, would likely be eligible for reduced assessment (due to the similarity of the regulatory frameworks between Australia and Europe) is supported.

It is understood that the TGA is unsure how many manufacturers would take up this option and, if it is of value to the TGA, ADIA is willing to consult with the TGA further and external stakeholders on this point.

ADIA has been a long-standing proponent of reforms to the regulatory standards associated with the domestic manufacture and supply of medical devices and believes that the best opportunity to reduce red tape in the sector is the alignment with existing frameworks available internationally. The comments within the TGA's documentation that the current regulatory requirements were aligned with those of the European Union was because the small Australian market "limits the feasibility of stand alone regulatory arrangements in Australia" is noted; however, ADIA believes that the Australian dental industry would be best suited when the Australian regulatory requirements align with those of comparable overseas dental product markets not just because the small Australian market makes development of unique regulatory regime difficult to achieve.

Establishment Of New Conformity Assessment Bodies —

In ADIA's discussions with the TGA, and in the TGA's paper canvassing reform implementation, the regulator has questioned whether there would be sufficient interest from appropriately credentialed bodies to establish themselves as conformity assessment bodies within Australia. ADIA appreciates the interest of the TGA in this matter; however, industry advice is that the TGA's concerns in this area are unfounded.

The size of the Australian market coupled with a strong and growing domestic medical device manufacturing capacity provides scope for a limited number of specialised businesses to work as competent authorities within the Australian regulatory system. It is likely that, in the initial stages, these would be modest in number yet the benefit that they will provide to the Australian market would be considerable.

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The TGA paper on reform implementation canvasses issues associated with the commercial viability of new TGA-designated conformity assessment bodies within Australia. The TGA has noted that one aspect would be that the use of such bodies would be an attractive option if the designated third party assessment times were more expeditious than TGA mandatory application audit times and that the cost for certification was in-line with the costs for application audits. It is noted that there may be other reasons and, as a matter of policy, these should be a matter for industry to determine and reform in this area should not be delayed if the TGA has concerns about the commercial viability of TGA-designated third party assessment bodies.

It is thought that the proposed process of allowing TGA-designated conformity assessment bodies will support the interests of businesses manufacturing dental products, and other medical devices, within Australia and exporting. Some of these businesses do rely upon the requirement, by some overseas regulators, for 'home market' regulatory approval and the proposed reforms are understood not to impact these businesses; however, ADIA recommends that the TGA engage in a process of continual industry consultation to ensure that this is the case.

With respect to the activities of the TGA working to designate conformity assessment bodies, ADIA is broadly supportive of the framework set out in the paper outlining the implementation pathway. There are some issues set out in the paper that ADIA takes this opportunity to comment on.

TGA Responsibilities —

The role of the TGA in designation, monitoring and controlling and the work of TGA-designated conformity assessment bodies is noted. To the extent that is possible, it would be preferable that this be undertaken in a manner that is consistent with the guidance published by the International Medical Device Regulators Forum (IMDRF). This will require the IMDRF to develop new materials in this area.

ADIA is supportive of the TGA in maintaining its regulatory maintenance activities on behalf of Australia; however, this will require the development of new TGA consultative mechanisms to ensure that it has properly consulted with new Australian conformity assessment bodies.

Conformity Assessment Body Operation —

The TGA has outlined potential requirements associated with an organisation seeking designation as a conformity assessment body. ADIA advises the TGA to limit the extent to which it seeks to be prescriptive in this regard.

ADIA believes that that TGA-designated conformity assessment body need only to demonstrate competency at an organisational level – that is the ability to deliver the required service – than meet and predetermined resourcing levels. By way of example, it needs only to have access to qualified and experienced staff (either on a part-time contract basis or secondment from an overseas office) as opposed to having them on staff. The TGA's paper outlines considerations for assessors (e.g. flexibility in scheduling, professional support, expertise back-up) that are commercial in nature and should not be a factor in TGA decisions on whether to grant an organisation status as an Australian conformity assessment body.

ADIA believes that in the development of criteria for designating Australian conformity bodies, the TGA's focus should be on the arrangements pertaining to the organisation and not its staff – as it stands the TGA seems almost to be straying into the areas of personal practitioner certification which is not the TGA's role.

TGA Funding Of Designation Activities —

That cost-recovery nature of the TGA's operations produces several anomalies where businesses in the dental industry, and the broader medical devices sector, are funding government activities that can be strongly argued are a matter of public interest and therefore the costs should be met from an annual budget appropriation rather than TGA fees and charges. ADIA is of the view that the TGA's activities associated with the designation of Australian notified bodies are regulatory responsibilities that should be met, in their entirety, from an annual budget appropriation and not from industry.

It is understood that the Australian Government, in a time of budget restraint, may not be inclined to provide the TGA with funding to undertake its regulatory activities. In this context ADIA believes that the TGA should seek funding of its activities to designate Australian notified bodies directly from those organisations seeking status as an Australian conformity assessment body.

ADIA is not supportive of funding the TGA's costs associated with designation of Australian notified bodies via the annual charges currently applicable to ARTG entries. Such a course of action would place an excessive and supererogatory burden on businesses that may have drawn no direct benefit from the reforms.

Competitive Neutrality —

The paper outlining the proposed implementation framework implies that the TGA itself will continue to operate as a conformity assessment body. In this scenario, the TGA will be competing with the private sector insofar as its conformity assessment body activities are concerned. This is not acceptable in an environment in which the TGA is in a position to subsidise, directly or indirectly, conformity assessment activities.

Consistent with the *Competition Principles Agreement* agreed to by the Council of Australian Governments (COAG), the Australian Government has committed to ensuring that publicly owned businesses do not enjoy any net competitive advantage simply because they are publicly owned. This provides an important framework in which the TGA must undertake its own conformity assessment activities.

ADIA recommends that once a private-sector organisation has commenced the process of seeking TGA-designation as a conformity assessment body, the TGA implements the necessary changes so that, consistent with competitive neutrality principles, its own conformity assessment activities enjoy no net competitive advantaging owing to its Australian Government affiliation.

Upon TGA-designated conformity assessment bodies commencing operation the TGA should seek independent, third-party assessment to ensure that the principles of competitive neutrality are upheld.

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Consistent Outcomes –

The success of these reforms will, to a large extent, be dependent on the conformity assessments undertaken by a TGA-designated conformity assessment body (within the scope of their endorsement) being treated in exactly the same fashion as a conformity assessment being undertaken by the TGA itself.

It should be noted that ADIA will not be seeking endorsement as a TGA-designated conformity assessment body; however, it is fully supportive of the direction of proposed reforms that will appropriately credentialed organisations to seek such endorsement. From the perspective of the TGA, the Australian Government's focus should be less on the commercial viability of such reforms, but instead on simply creating the market opportunity for TGA-designated conformity assessment bodies to operate sustainability.

Specific Recommendations –

- ADIA is therefore supportive of a TGA designated Australian conformity assessment body to undertake certification for only some types and / or classes of medical devices.
- The use of TGA-designation of Australian conformity assessment bodies is unlikely to adversely impact the interests of Australian businesses seeking access to overseas markets that require 'home market' regulatory approval; however, ongoing industry consultation on this point is recommended.
- The TGA's costs associated with designation of Australian notified bodies should not be funded via the annual changes currently applicable to ARTG entries, but by (new) charges levied on those business seeking designation.
- Consistent with competitive neutrality principles, the TGA's own conformity assessment body activities enjoy no net competitive advantaging owing to its Australian Government affiliation.
- ADIA believes that in the development of criteria for designating Australian conformity bodies, the TGA's focus should be on the arrangements pertaining to the organisation and not its staffp.

ADIA supports the direction of these reforms as they are consistent with the dental industry's interest in securing reforms that ensure the medical device regulatory framework is based on a risk management approach designed to ensure public health and safety, while at the same time freeing industry from any unnecessary regulatory burden.

We look forward to further consultation with the TGA on concerning these reforms.

Yours faithfully

Troy R Williams FAIM MAICD
Chief Executive Officer