Dear Sir / Madam,

We have reviewed the response of the Australian Dental Industry Association (AIDA) to the TGA Proposals – Reforms for the medical devices regulatory framework.

We support the ADIA proposals and echo the concerns that some of the proposals especially 3 (I) and 3 (II) substantially alter the existing regulatory arrangements and will result in very large initial one-off costs to business as well as significant ongoing costs.

One additional suggestion we have for 3 (I) is to consider focusing on the Australian Declaration of Conformity. Instead of making separate entries that will incur costs by having to be evaluated continue to keep the entry at the GMDN level but request that the declaration of conformity should list the significant different models (not colour changes or left / right handed variations) and be supported by the EC certificates. This way any additional "model" that a sponsor wishes to introduce will only require an update of the declaration to be submitted replacing the previous entry. If necessary it should be possible to link the declaration to the public domain so that the public can confirm that various models are registered. This would still need some considerable time to prepare and update. We would suggest the ramp up would need to be extended to at least two years.

Thank you for giving us the opportunity to comment on the proposals.

Best Regards

Ron Hodge

Regulatory & Compliance Manager

Henry Schein Halas

Everything Dental