

Offices of Devices Authorisation- Therapeutic Goods Administration
PO Box 100,
Woden ACT 2606

13th December 2010

TGA Proposed Regulatory Reforms

I am most concerned about two of the proposed changes and the effect that these changes will have on my business as a supplier of German dental products to the dental profession.

The Proposals are-

Proposal 3 (i) ARTG Inclusion changes:

This proposal substantially alters the existing regulatory arrangements for businesses and would result in a very large initial one-off cost to my business as well as significant ongoing costs.

Proposal 3 (ii) Enhancing identification of approved devices:

This proposal substantially alters the existing regulatory arrangements for businesses and will result in a very large initial one-off cost to my business and again significant ongoing costs.

I would ask that you kindly consider my comments and when meeting to discuss the proposed changes.

Yours Sincerely



Dee Macpherson
Director