ZEISS CARL ZEISS VISION

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Dear Sir

The following submission was also emailed to devices@tga.gov.au.

In response to the Discussion Paper "Reforms in the Medical Devices Regulatory Framework" dated 25 October 2010, on behalf of Carl Zeiss Vision, I would like to table the following feedback, specifically to Proposal 3(ii) "Enhancing the identification of approved devices":

- Our company is a manufacturer of customised spectacle lenses and also a sponsor of customised and stock spectacle lenses that are all Class 1, Non-sterile, Non-measuring devices. As a sponsor of customised and also finished stock spectacle lenses (lenses that are in their final form except for being cut to the patient's frame shape) that are sold only to eyecare professionals, these lenses may be manufactured by a number of manufacturing locations around the world, each with their own ARTG number (because of several manufacturing sources) **but all under the same GMDN number**. Proposal 3(ii) requires that the ARTG number be published on the information that accompanies the device. Each manufacturing plant of which we are a Sponsor, is a global supplier and as such uses globally standardised packaging for all our markets around the world. If we are now required to add the ARTG number to the unit packaging, this will be a significant cost burden, either by requiring all manufacturing plants to change their local packaging labelling, or we, as sponsor, apply an additional label to the packaging when the product is imported and distributed in Australia. For a low risk medical device like Class 1, we believe that the extra bureaucracy and costs associated with adding an ARTG number to a label or accompanying documentation serves no real value to customers. **We would therefore propose that Class 1 medical devices, especially Non-sterile, Non-measuring, be exempt from Proposal 3(ii).**

- If our proposal is not accepted as reasonable by the TGA, to reduce the cost burden, we propose that instead of applying the ARTG to each lens packaging, we include a list of all our ARTG numbers of which we are sponsor or manufacturer that cover our manufacturing locations and this information would be printed either **on the shipping list** that accompanies shipments that are dispatched to domestic customers, or on the invoice that can be sent up to 5 days later (ie not technically accompanying the shipment). **We propose to list all ARTG numbers for which we are Sponsor or Manufacturer** (because they are all under the same GMDN number) rather than trying to only include ARTG numbers for that particular delivery because orders can be made up

of hundreds or even thousands of lenses and the mix could come from several sources, even for the same lens type. It would be very costly logistically and we believe serves no particularly useful information of value to the customer, especially for a Class 1, Non-sterile, Non-measuring device, to individually link ARTG numbers to the mix of lenses in each particular customer shipment. Additionally, the shipping document accompanying each shipment includes our company name and Australian address, and for finished stock lenses, all unit lens packaging is individually labelled with our international company name, and corporate web address (which also links to our Australian office), so in the extremely unlikely event that a customer or the TGA wanted to know the specific ARTG for a particular lens, this would be a very simple matter of contacting our company using any of these traceable sources.

Yours sincerely

Robin Barlow
Director Quality: Asia & Australia