

22 December 2017

Therapeutics Goods Administration
info@tga.gov.au

TGA consultation-proposed-regulatory-changes-related-personalised-and-3d-printed-medical-devices

Royal Australian New Zealand College of Ophthalmologists (RANZCO) welcomes the opportunity to respond to the proposed-regulatory-changes-related-personalised-and-3d-printed-medical-devices. In response, RANZCO highlights the potential impact on the category of low-risk devices exempt from the regulation of custom-made medical devices, which currently includes prescription lenses and glass eyes, among other products. It is understood that the new proposed regulatory changes will revisit this exemption and may introduce new regulations that would impact prescription lenses, and other non-implantable ocular prostheses, therefore, RANZCO recommends:

- clear distinctions made between devices which are implanted, as opposed to devices which contact non-skin surfaces (such as contact lenses), versus devices such as glasses which contact only the skin, and different regulations are applied to each category

Regarding the definition of medical device 'manufacturer', RANZCO concedes that health care providers and hospitals are generally not 'manufacturers'. However, in a situation where a hospital or health care provider owns a piece of equipment which either significantly modifies, or even produces the actual device (for example, through 3D printing), there does need to be some regulatory framework. RANZCO supports:

- hospitals and health care providers to reach best practice standards (in alignment with the manufacturer of the whole production package, including the printer).

Should you require further clarification on these issues, correspondence should be directed to Margaret Lum. mlum@ranzco.edu.au. Kindly consider recommendations by RANZCO when implementing proposed regulatory changes.

Yours sincerely


David Andrews
RANZCO CEO