OPTOMETRISTS
ASSOCIATION AUSTRALIA

20 August 2012

TGA Medicine Labelling and Packaging Review
Therapeutic Goods Administration
Department of Health and Ageing
Email: labellingreview@tga.gov.au

To whom it may concern

Optometrists Association Australia submission to the Therapeutic Goods Administration consultation regarding Medicine labelling and packaging

Optometrists Association Australia (OAA) welcomes the opportunity to provide comment on the proposed regulatory changes of relevance to the labelling and packaging of medicines.

OAA is the peak professional body for Australian optometrists. The Association represents over 4,000 members and close to 95% of optometrists registered with the Optometry Board of Australia.

Optometrists use medicines as part of their clinical practise, including medicated eye drops to conduct diagnostic procedures and anesthetics to perform tonometry. Optometrists who have scheduled medicines endorsement of their registration are also able to prescribe a select number of topical ophthalmic medicines, the majority of which attract a subsidy under the Pharmaceutical Benefits Scheme. The Association's interest in the labelling and packaging of medicines thus relates to the impact of labelling and packaging requirements on quality use of medicines by optometrists in their practice and by patients using either prescribed or non-prescription ophthalmic medicines.

OAA notes general support for the measures to enhance the safe and effective use of medicines proposed by the Therapeutic Goods Administration (TGA) through their consultation paper on medicine labelling and packaging. We believe the proposed changes to increase the prominence of the active ingredient on packaging and labelling and support differentiation of products through regulations associated with look-alike and sound-alike medicine names, and look-alike packaging, are important to promoting patient safety by reducing misuse.

We similarly support the proposed regulatory change to standardise the placement and presentation of the Medicine Information Box, as a well-targeted measure to promoting patient safety by ensuring patients and health professionals can readily access critical safety information presented in a consistent manner. Further, we support the proposed regulatory changes relating to affixing of dispensing labels, which would designate a space for affixing labels to ensure labels obscure minimal information contained on medicine packaging or labelling.

Regulations relating to small containers (20ml capacity or less) have particular relevance in optometry where eye drops are commonly used or prescribed. In relation to the labelling and packaging of small containers, OAA strongly supports the proposed regulatory changes that would require all small containers to be enclosed in a primary pack that complies with all labelling requirements and that also encloses a pack insert detailing instructions for use of the medication. As small containers of eye drops are frequently stored outside of their primary packaging, OAA further supports recommended

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regulatory changes to ensure all the key information required by the health professional or patient is clearly noted on the container. OAA also supports the recommendation to require a space to be allowed for a pharmacist to affix a folded dispensing sticker without obscuring key information. OAA notes that it is not clear in point 7.3 (p.37) of the consultation paper, whether this requirement pertains to the container itself or the primary packaging it is contained within. For practicality for the dispenser and patient we recommend that this requirement be considered relevant to the primary packaging in the case of small containers.

With regard to the recommended regulatory changes in relation to pack inserts, OAA supports proposed amendments that would require pack inserts to be concise and without extraneous information, particularly without advertising materials. We further support changes that would prevent inserts from being printed on the inside packaging, which limits the accessibility of key information for patients and health professionals.

OAA would particularly like to emphasise the importance to patient safety of ensuring to the greatest extent possible that all text - and particularly that outlining information critical to safe and effective use - used in the labelling and packaging of medicines is of a font-size that is clearly legible. We appreciate that the dimensions of small containers demand presentation of critical information in a small font size and note that the TGA is proposing a minimum letter height of 1.5mm in these cases. OAA recommends the TGA consider recommending a further regulatory change to require pack inserts to repeat critical safety information contained on the container label or primary pack, where the information on the label or pack is below a specified size, in a larger font. If this is not practical, an alternative may be to require packaging to clearly detail where this information is available online in a format that enables size to be increased. This has particular importance to optometry where patients can commonly experience a degree of vision impairment and where medicines are often provided in small containers.

Optometrists, with expertise in vision and acuity, are well placed to advise on contrast and legibility. OAA would be happy to support the TGA in accessing this advice to support the further definition of regulations to ensure medicine labels are clearly legible.

Thank you for this opportunity to comment.

Yours sincerely,

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Chief Executive Officer