

COUNCIL PAPER
PRIVATE & CONFIDENTIAL

Date: 9 December 2015

Out-of-session endorsement

Subject: RACGP response to the draft Labelling order for medicines.

This document has been submitted by Dr Evan Ackermann, Chair of the RACGP Expert Committee – Quality Care, and is endorsed by the President and Chair of Council (Out-of-Session Endorsement).

Recommendation

That Council ratifies the endorsement of the RACGP response to the draft labelling order for medicines as endorsed by the President and Chair of Council (Out-of-Session).

Background & Justification

Improving the quality of medicines naming, labelling and packaging in Australia is an ongoing aim of the Therapeutic Goods Administration (TGA). In response to comments received during the consultation on medicine labelling conducted in late 2014, new draft Orders have been developed.

As part of a targeted consultation process, the TGA has invited the RACGP to provide feedback on proposed changes and *Guideline for medicine labels*.

In developing a response, the Quality Care team consulted with members of the RACGP Expert Committee – Quality Care. Our brief response focuses on the need for consistency, clarity and readability of information for health users of different literacy levels.

Strategic alignment

1. Leadership and advocacy for the profession - To be the leading professional voice representing its members and the wider profession, proactively advocating for an effective and sustainable primary healthcare system:

- 1.3. Engage with external stakeholders and maintain an influential profile with relevant organisations, including government and other professional bodies
- 1.5. Increase awareness of the leadership and advocacy role of the College

Budgetary impact

The cost associated with preparation of this letter has been absorbed by the Quality Care Unit budget.

Risk identification

This request for out of session endorsement is made on the basis that checks have been conducted and it is confirmed that the feedback will not alter existing College policy.



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Communication strategy to members and stakeholders

Within 5 working days following the notification by the General Manager – PPI, the Quality Care team will coordinate the recording of the notification in the College Record Management system and publication of the item on the College website (www.racgp.org.au/yourracgp/news/reports/).

Appendices

- RACGP submission (TGA template)
- Summary table of amended requirements between TGO 79 and TGO 91 92
- Draft Therapeutic Goods Order TGO 91 Prescription and related medicines
- Draft Therapeutic Goods Order TGO 92 Non-prescription medicines
- Guidance document for medicine labels - amended consultation copy