RACP
Specialists. Together
EDUCATE ADVOCATE INNOVATE

# RACP Submission: Consultation on Complaints Handling - Advertising therapeutic goods to the public

## Consultation on Complaints Handling - Advertising therapeutic goods to the public

The Royal Australasian College of Physicians (RACP) welcomes the opportunity to provide comments to the Therapeutic Goods Administration's consultation on the proposed complaints handling model.

The RACP welcomes the TGA's role as the single entity presiding over the handling of therapeutic advertising complaints in Australia, which is a task of significant national importance in preventing misleading or false therapeutic goods advertising and protecting consumers.

The RACP supports the TGA's proposed priority-based complaints management model, comprised of a complaints process, reporting of outcomes (with publishing of details in cases which are classified as being of medium, high and critical priority) and key TGA performance indicators.

However, there is no mention of which committees will have the overall responsibility for investigation and final decision-making as well as how such decisions will be made in the consultation paper. The RACP proposes that the TGA should consider convening separate committees, comprising doctors, pharmacists and at least two experienced consumers, to provide independent advice in relation to complaints about advertisements for different classes of medicines (for example one for prescription medicines and another for over-the-counter medicines).

We also consider that a good complaints handling model should be able to demonstrate its effectiveness and responsiveness not only in operation and enforcement, but also in the speed with which non-compliant advertising is removed; as well as ensuring it is not reinstated until it is compliant with legislative requirements.

Furthermore, with the two new approval pathways being almost implemented in Australia, the RACP believes that it is of significant importance for the TGA to develop and implement additional safeguards specific to the advertising of early market access medicines. These safeguards are required because these medicines, which are granted under the provisional approval pathway where the approvals are based on provisional evidence with a lack of clinical phase II and III data, are characterised by uncertainties in terms of their safety and effectiveness.

On another note, we are very concerned about the advertising of unapproved cannabis products by new cannabis companies as well as the direct advertising and marketing of approved cannabis products to physicians, considering the current very limited evidence base for medicinal cannabis. In this light, we urge the TGA to examine the current process regarding advertising of unapproved cannabis products and whether there is a need to ramp up related pharmacovigilance efforts.

Should you require any further information regarding this response, please contact Bella Wang, Policy Officer at Bella.Wang@racp.edu.au or on +61 2 9256 5432.