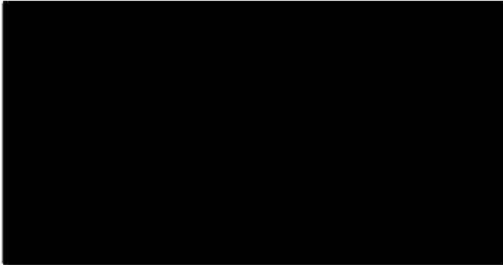


15 June 2018



Re: Consultation on Complaints handling – Advertising therapeutic goods to the public

Thank you for providing the opportunity to the Royal College of Pathologists (the College) to comment on the proposed complaints procedure in relation to advertising of therapeutic goods to the public.

The College has no specific comments about the complaint process per se. However we are concerned at the lack of distinction in the opening paragraphs between advertising and information. Whilst agreeing that vulnerable patients should be protected from promotional literature which may raise inappropriate expectations or demands for testing, regulators and providers should not lose sight of the need of vulnerable patients for reliable information about the tests available. It is not sufficient to leave the provision of this information to patients' doctors. Many doctors are not familiar with the strengths and limitations of new pathology tests, particularly in the discipline of genetics. If providers of such tests are precluded from providing information to the public, the end result is that vulnerable patients are denied access to the very information they need to be involved in responsible decision-making.

It will be imperative that the TGA explicitly recognises the potential for test providers (the experts regarding a test) to provide information to patients and the public. That license must carry responsibilities and the providers should be accountable for the information they provide and the manner in which it is presented. The explicit recognition that such information can be responsibly provided will be essential for the interpretation of the complaint process outlined in this document. In the absence of such recognition, the management of complaints could simply result in patients and the public knowing less about their investigations and being disenfranchised in the decision-making.

If you have any further questions or comments please do not hesitate to contact me at debrag@rcpa.edu.au.

Yours sincerely



Dr Debra Graves
Chief Executive Officer