The Royal Australian & New Zealand College of Psychiatrists

Your Health in Mind

23 March 2017

Complementary Medicines Reform Section
Complementary and OTC Medicines Branch
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606

Dear Sir/Madam

Re: Reforms to the regulatory framework for complementary medicines: Assessment pathways

Thank you for inviting the Royal Australian and New Zealand College of Psychiatrists (RANZCP) to contribute to the Therapeutic Goods Administration's (TGA) consultation regarding reforms to the regulatory framework for complementary medicines. The RANZCP represents around 4000 fully qualified psychiatrists in Australia, many of whom have specific interest in this matter. As such, we strongly support the purpose of the reforms and welcome the opportunity to contribute.

The RANZCP is concerned at reports that consumers describing symptoms of mental ill health are being sold products that have little or no efficacy. Although the RANZCP acknowledges the potential benefits of many complementary medicines, it is essential that the industry is properly regulated to protect consumers against misleading information and ineffective and/or dangerous products. As such, we support the introduction of a new assessment pathway for complementary medicines which has the potential to:

- improve the information available to consumers
- increase transparency
- mitigate health risks
- encourage improvements in the evidence base upon which claims of efficacy are made.

The RANZCP also supports the other reforms proposed including the development of a list of core permitted indications which can be modified with pre-approved qualifiers (Option 2).

However, the RANZCP believes that the proposed framework could be improved with some additional regulations including the mandatory testing of all medicines to ensure that they actually contain what they claim, and that they are free from contaminants. This has not always been the case. We would also support a requirement that complementary medicines be sold in differentiated sections of retail pharmacies.

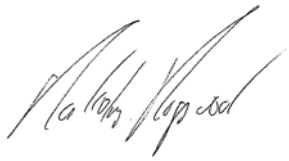
309 La Trobe Street, Melbourne VIC 3000 Australia
T +61 3 9640 0646 F +61 3 9642 5652
ranzcp@ranzcp.org www.ranzcp.org
ABN 68 000 439 047

The RANZCP supports the proposed criteria to allow sponsors to claim that the efficacy of their products has been assessed (the use of a 'claimer') and would support a highly visible identifier such as a symbol and accompanying statement. However, we would suggest the mandatory inclusion of a statement and/or visual identifier denoting the level of efficacy assessment – this would ensure that medicines that have not been subject to assessments would be clearly identifiable by consumers. This may be in the form of a symbol and accompanying statement for assessed medicines and a statement for non-assessed medicines. Otherwise, consumers are at risk of assuming there is evidence where there is not, or being misled.

With regards to indications relating to mental health, the RANZCP supports the continued prohibition of representations regarding the treatment, cure or prevention of mental illness. However, although we support the inclusion of beneficial effects on one's psychological state as a low level indication, we note that these must be carefully worded and would encourage the TGA to utilise psychiatric expertise to inform the development of permitted indications regarding enhancement of psychological states.

If you would like to discuss any of the issues raised in this letter, please contact Rosie Forster, Senior Department Manager, Practice, Policy and Partnerships via rosie.forster@ranzcp.org or by phone on (03) 9601 4943.

Yours sincerely



Professor Malcolm Hopwood
President

Ref: 0658o