# AUSTRALIAN COMMISSION ON SAFETY AND QUALITY IN HEALTH CARE

TRIM: 78625

Ian Holland
Secretary, Standing Committee on Community Affairs
PO Box 6100
Parliament House
CANBERRA ACT 2600

Dear Mr Holland

***Therapeutic Goods Amendment (2013 Measures No. 1) Bill 2013***

Thank you for your e-mail of 5 April 2013 inviting the Australian Commission on Safety and Quality in Health Care (the Commission) to comment on the *Therapeutic Goods Amendment (2013 Measures No. 1) Bill 2013.*

I note that many of the amendments proposed are technical in nature and clarify terminology and the operation of the Act. There are, however, a number of amendments that seek to improve the safety and quality of the use of therapeutic goods in this country, which I support. These include giving the Minister the capacity to specify, by legislative instrument, products that will not be classified as therapeutic goods for the purposes of the Act and enabling the Secretary to remove particular products from the Register that are no longer therapeutic goods within the definition in the Act.

There is no doubt that the effective functioning of the Therapeutic Goods Administration and the use of the Register are important to the safety, quality and efficacy of therapeutic goods in Australia. They allow consumers, clinicians and other stakeholders to have faith and confidence in the regulation of goods used for therapeutic benefit. The operation of the current Act has resulted in a number of products being listed on the Register, sometimes with a limited evidence base and sometimes where the therapeutic claim is no longer being made. The simple fact of listing of these products on the Register may inadvertently give consumers and clinicians a sense of support or warranty that is neither justified nor intended.

There is currently limited capacity to remove products from the Register where these circumstances exist and the provision of this additional capacity to the Secretary is a valuable addition in maintaining the quality of the Register. This can only strengthen the reassurance that the application of the Act can provide.

I am also pleased to see the explicit recognition in Schedule 7, Section 2, of safety, quality and efficacy as essential criteria to enable the Secretary to impose requirements relating to a therapeutic good. This clear enunciation of safety and quality as fundamental drivers within the Act is welcome.

GPO Box 5480, Sydney NSW 2001
Level 7, 1 Oxford Street, Darlinghurst NSW 2010
T: (02) 9126 3600 | F: (02) 9126 3613 | W: www.safetyandquality.gov.au | E: mail@safetyandquality.gov.au

Finally, the strengthening of the requirements for the provision of information to the public and the quality of that information is very much supporting the Australian Safety and Quality Framework for Health Care developed by the Commission and endorsed by all Health Ministers in November 2010.

Thank you again for the opportunity to comment on the Bill.

Yours sincerely

Professor Debora Picone AM
**Chief Executive Officer**
Australian Commission on Safety and Quality in Health Care

17 May 2013