

13 June 2013

complianceconsultation@tga.gov.au

Re: Evaluating the feasibility of a new-to-market risk communication scheme for therapeutic goods

The Society of Hospital Pharmacists of Australia (SHPA) is the national professional organisation for over 3,000 pharmacists, pharmacists in training, pharmacy technicians and associates working across Australia's health system. SHPA is the only professional pharmacy organisation with a strong base of members practising in public and private hospitals and other health service facilities.

SHPA was represented at the consultation workshop held 29 May and offers the following additional comments.

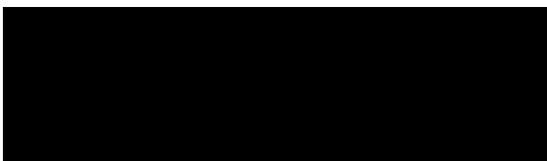
SHPA believes that the proposed selection criteria will lead to better targeting of adverse event reporting and increased pharmacovigilance.

SHPA fully supports the proposed scheme as a communication tool for healthcare professionals and consumers for new-to-market medicines on the Australian market. The inclusion of a new medicine in the scheme should be communicated through all mechanisms where the trade name is listed: i.e. packaging, PI, CMI and usual texts e.g. AMH, therapeutic guidelines etc.

Finally SHPA believes that the scheme should apply to all newly licensed active ingredients, new combinations, new routes of administration and significant new indications. In addition SHPA supports automatic removal of products after a pre-determined time period and suggests a minimum three year listing with an additional period of time where the risk management plan identifies that the medicine has a higher than usual risk profile.

If you would like to discuss the issues raised in this submission or require further information please contact Nicki Burridge (nburridge@shpa.org.au or 03 94860133).

Yours sincerely,



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