
From: Shane Carney
Sent: Tuesday, 8 July 2014 5:46 PM
To: Adjudication
Cc:
Subject: Medicines Australia Limited application for revocation of authorisations A91316-A91320 and substitution of new authorisations A91436-A91440-interested party consultation.

Categories: Submission

Thank you for the opportunity to review Medicine Australia's Code of Conduct Edition 18. Overall this periodic process of updating their Code of Conduct by Medicines Australia has been very well performed. I only have one concern which relates to Section 8 :Product Familiarisation Programs (PFP's).

When new prescription medicines have been approved for use by the Therapeutics Goods Administration's (TGA) Advisory Committee on Prescription Medicines (ACPM) ,in their rush to get their product to market , PFP's will sometimes be set up by companies prior to PBS approval to subsidise the product. This action can facilitate pressure by prescribers , patients and their families on the TGA's Pharmaceutical Benefits Advisory Committee(PBAC). This happened recently with Dabigatran , an oral anticoagulant.

While there may be a place for such behaviour with an urgently needed preparation , industry must be responsible in this area since most new drugs have had a limited period of time for evaluation and have often not been used in a wide range of patients. It may take time for practitioners to become familiar with a product often with significant side effects.

Consequently section 8 should contain a section that acknowledges this issue . Unless exceptional circumstances , PFP's should only be used when a drug has been considered by PBAC and added to the PBS.

Shane Carney FRACP