



AUSTRALIAN MEDICAL
ASSOCIATION

ABN 37 008 426 793

T | 61 2 6270 5400

F | 61 2 6270 5499

E | info@ama.com.au

W | www.ama.com.au

42 Macquarie St Barton ACT 2600

PO Box 6090 Kingston ACT 2604

AMA submission – TGA proposed monitoring medicines enhancements

ReformsandOperations@health.gov.au

The AMA supports a comprehensive product vigilance system in line with international best practice, and the development of proactive product vigilance strategies that enhance the robustness of post market surveillance processes and improve data linkages.

The AMA therefore fully supports the TGA's plans and activities to enhance and increase its monitoring of medicines post-market.

Although not explicitly articulated in the consultation discussion paper, the AMA expects that the TGA will seek advice about the implementation of activities impacting on medical practitioners and other health professionals, either through its existing expert and stakeholder advisory committees or in further consultation processes. For example, practitioner advice will be necessary to help inform the most effective way of introducing the black triangle scheme and ensuring it is noticed, such as via prescribers' desktop software. Similarly, any changes to the Product Information documentation should be preceded by consultation and trialling with practitioners who will rely on them.

APRIL 2017

Contact

Georgia Morris
Senior Policy Advisor
Medical Practice Section
Ph: (02) 6270 5466
gmorris@ama.com.au