

17 August 2017

**Re: TGA Consultation: Introduction of the black triangle scheme**

MS Research Australia is the largest national not-for-profit organisation dedicated to funding and coordinating multiple sclerosis (MS) research in Australia. Our goal, as part of a worldwide effort, is to accelerate research into the cause, better treatments for, and prevention of MS, with the aim of ultimately finding a cure for MS.

A range of disease modifying medications are available for people with the relapsing form of MS. New medications for both relapsing and primary progressive MS are also in the pipeline and/or close to approval.

It is very important that people with MS have access to affordable, effective and safe medications. It is also important that they understand both the potential benefits and risks of their medications, and that they understand the necessary steps, processes and reviews that go into ensuring medications are safe to use.

Introducing the black triangle scheme will help raise awareness and reassure patients that monitoring the safety of medicines does not end with clinical trials and the approval and listing of the medication on the ARTG.

However, it is also important that patients are not unnecessarily alarmed about what may only be theoretical risks of their medications. The suggested wording for the black triangle box may make patients think that there is perhaps something to be concerned about in relation to their medication. As such our suggestion would be to adjust the wording in the box on the patient Consumer Medicine Information sheet so that it instead reads:

‘As a new medicine, this medicine is subject to additional ongoing monitoring. This will allow quick identification of any potential changes required to the safety information. You can help by reporting any side effects you may experience.’

Thank you for the opportunity to comment on this matter.  
Kind regards



Dr Lisa Melton, Head of Research  
on behalf of MS Research Australia