



Australian Government

**Department of Health,
Disability and Ageing**

Dr Eng Pawet Wajss
Faculty of Energy and Fuels, AGH University of Krakow
wajss@agh.edu.pl

Dear Dr Wajss

Thank you for your letter to the Department of Health, Ageing and Disability regarding the safety of muscarinic receptor antagonists, and for providing a copy of your publication in *OphthaTherapy, Therapies in Ophthalmology*.

The Therapeutic Goods Administration (TGA) continually monitors the safety of all medicines in Australia. We have not confirmed a safety signal in relation to retinal damage secondary to solar radiation exposure for muscarinic receptor antagonists currently registered in Australia. Safety signals for specific medicines may be detected via statistical analysis of spontaneous adverse event reports made to the TGA by patients, healthcare professionals, pharmaceutical companies, and health jurisdictions, or via publications in the medical literature, publications in mainstream media, or liaison with international counterpart regulators. If a signal is detected, we will assess it to determine the nature, magnitude and significance of the concern, as well as the impact on the overall benefit-risk profile of the medicine. If a safety issue is confirmed, we will take regulatory action to mitigate the risks. Your published work will be taken into consideration as part of a literature review to support investigation of any future safety signals detected by the TGA for muscarinic receptor antagonists.

We also work closely with pharmaceutical companies (also known as sponsors) and international regulators to ensure that accurate and up-to-date safety information is included in Australian Product Information (PI) documents. Information about how we monitor the safety of medicines and other therapeutic goods is also available on our website at: www.tga.gov.au/safety/safety-monitoring-and-information.

Sponsors have pharmacovigilance responsibilities for all the medicines they have registered or listed on the Australian Register of Therapeutic Goods (ARTG). Further information about the obligations of sponsors is available on our website at: www.tga.gov.au/resources/guidance/pharmacovigilance-responsibilities-medicine-sponsors.

I applaud your efforts in promoting eye protection through the Cover Eyes campaign. However, the TGA respectfully declines the invitation to sponsor the campaign. Thank you and good luck.

Yours sincerely

A handwritten signature in dark ink, appearing to be 'DD' followed by a long, horizontal, wavy line.

Dr Daniel Dascombe
Acting Principal Medical Adviser
Pharmacovigilance Branch
Medicines Regulation Division
10 December 2025