

Health Products and Food Branch Direction générale des produits
de santé et des aliments

Marketed Health Products Directorate
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Dr. Eng. Pawel Wajss
Faculty of Energy and Fuels, AGH University of Krakow
Al. A. Mickiewicza 30, 30-059
KRAKOW, Poland
(wajss@agh.edu.pl)

Re: Muscarinic Receptor Antagonists (Parasympatholytics)

Dear Dr. Wajss:

Thank you for your correspondence, dated February 20, 2025, regarding the safety of muscarinic receptor antagonist drugs. It was forwarded to the Marketed Health Products Directorate (MHPD) for response.

The health and safety of Canadians is Health Canada's top priority. The Department's mandate as the regulator of health products involves administering the *Food and Drugs Act* and the *Food and Drug Regulations* to help Canadians maintain and improve their health.

Before a health product is approved in Canada, the Department conducts a rigorous scientific review of its safety, efficacy and quality. An authorization is only issued when the benefits of the product outweigh the risks of its use as intended based on the information available at the time.

Health Canada continues to monitor the safety of authorized health products available on the Canadian market to ensure the benefits of the product continue to outweigh its risks. When new safety issues are identified, Health Canada takes action, which could include communicating new safety information to Canadians and healthcare professionals or changing the recommended use of the health product, or if warranted, removing the health product from the Canadian market.

Detailed information, including side effects associated with a marketed health product, is provided in its official Canadian Product Monograph (CPM), which is updated to reflect new safety information, as required, and can be accessed using the [Drug Product Database](#). This information helps to ensure that both prescribers and patients have access to information to guide their decisions about whether or not to use a

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particular product. The CPMs for this class of drugs (including atropine, tropicamide, and cyclopentolate) already include labelling regarding ocular adverse events associated with its use, such as light sensitivity and the need for bright light protection.

Moreover, the safe use of a medication is a shared responsibility. While Health Canada evaluates the overall benefits and risks of a health product, the prescribing of drugs and patient counseling are part of the 'practice of medicine' or 'practice of pharmacy' and are regulated provincially and territorially by the various professional colleges. Health Canada also works closely with manufacturers to implement risk mitigation measures for risks associated with the use of authorized health products. The Department uses several tools to inform and educate patients on these risks including, but not limited to, product labelling, and distribution of patient education and counselling materials. In addition, Health Canada encourages manufacturers to engage with physicians and pharmacists to ensure the appropriate implementation of these measures.

Health Canada will review the study that you shared regarding the risk of retinal damage associated with muscarinic receptor antagonists and in turn assess the need for further action to help protect the health and safety of Canadians as deemed applicable.

You had also requested the sponsoring of the *CoverEyes* campaign; Health Canada's role does not include sponsoring international social campaigns.

Thank you for taking the time to write and share your publication and concerns with Health Canada.

Sincerely,

We hope this information is helpful to you.

Marketed Health Products Directorate
Email: mhpd-dpsc@canada.ca