



Canadian Société  
Ophthalmological canadienne  
Society d'ophtalmologie  
EYE PHYSICIANS | MÉDECINS ET CHIRURGIENS  
AND SURGEONS | OPHTHALMOLOGISTES  
OF CANADA | DU CANADA

March 26, 2018

Mr. Kyle Steiger  
VP Ophthalmology Franchise  
Novartis Pharmaceuticals Canada Inc.  
385 Bouchard Blvd.  
Dorval, QC H9S 1A9

Mr. Stu Fowler  
GM Alcon Canada  
Alcon Canada Inc.  
2665 Meadowpine Blvd.  
Mississauga, ON L5N 8C7

Dear Mr. Steiger and Mr. Fowler,

In response to Novartis/Alcon's decision to discontinue Isopto Atropine 1%, as outlined in your letter dated March 20th, 2018, the Canadian Ophthalmological Society (COS) has discussed the impact this discontinuation will have with representatives from the following sub-specialty societies: the Canadian Association of Pediatric Ophthalmology and Strabismus (CAPOS), the Canadian Glaucoma Society (CGS), the Canadian Retina Society (CRS), and the Canadian Uveitis Society. Our joint response to the discontinuation follows.

We understand that Novartis/Alcon have decided to discontinue the manufacturing of Isopto Atropine 1% due to a December 2017 update issued by the United States Pharmacopeia (USP), of which Health Canada is a Member Organization. We also understand that complying with the new requirements would require extensive changes to the facility where Isopto Atropine 1% is manufactured.

Isopto Atropine 1% is a critical drug for many of our members' patients. The only substantially equivalent drug (Homatropine) was discontinued in 2016. Discontinuing Isopto Atropine 1% will have a significantly negative effect on a variety of patients undergoing ophthalmic treatment.

Members of CAPOS regularly use Isopto Atropine 1% in the practice of pediatric ophthalmology for the treatment of amblyopia, which affects as many as 5% of children. While patching had been the mainstay of treatment, the recent Pediatric Eye Disease Investigator Group ([PEDIG](#)) studies demonstrated that Isopto Atropine 1% was as effective as patching therapy. Now it is widely used for this purpose, often with better compliance and thus better results. Isopto Atropine 1% is also regularly used in the management of pediatric cataracts, glaucoma, and uveitis. Isopto Atropine 1% is also widely used by pediatric ophthalmologists and optometrists to slow the progression of myopia, which currently affects 30% of the population and is increasing. In some populations the incidence is reported to be more than

75%. Isopto Atropine 1% was popularized for treating myopia in Asian countries after the ATOM studies (Atropine Treatment of Myopia). It is now becoming widely used in Canada for this purpose. CAPOS strongly believes there is currently no other medication that could be substituted to save sight in treatment of these problems.

Members of the CGS use Isopto Atropine 1% extensively to prevent blindness. Blinding glaucoma variants such as ciliary block/malignant glaucoma require Isopto Atropine 1% as initial treatment to avoid surgery and reduce the risk of irreversible visual loss. Patients with inflamed eyes and iris bombe/pupil block may require Isopto Atropine 1% to break posterior synechiae and avoid acute as well as chronic glaucoma-related visual loss. Postoperative patients may also require Isopto Atropine 1% to prevent and treat choroidal effusions and hypotony, again to avoid irreversible visual loss. Another important use for Isopto Atropine 1% is in hyphemas, specifically after trauma where it is used for permanent dilation, which decreases the risk of rebleeding. The CGS strongly feels there is no other medication that can match the benefit of Isopto Atropine 1% in preventing blindness for patients in several specific glaucoma settings.

In addition to the uses outlined above, members of the CUS regularly rely on the use of Isopto Atropine 1% in the treatment of their patients, and members of the CRS rely heavily on the use of Isopto Atropine 1% for vitreoretinal surgery dilation and postoperatively to help in cases where a patient has a gas- or oil-filled eye.

As you can see, Isopto Atropine 1% is widely used across ophthalmology. It is critical in preventing blindness and ensuring the best possible outcomes for our patients. We strongly urge you to consider all possible alternatives to discontinuing Isopto Atropine 1%, and we would be pleased to work with Novartis/Alcon and other stakeholders to find a solution.

Sincerely,

Dr. Guillermo Rocha  
President, Canadian Ophthalmological Society

Dr. Catherine Birt  
President, Canadian Glaucoma Society

Dr. Amin Kherani  
President, Canadian Retina Society

Dr. Jean Deschênes  
President, Canadian Uveitis Society

Dr. Michael O'Connor  
President, Canadian Association of Pediatric  
Ophthalmology and Strabismus