Common Drug Review
Patient Group Input Submissions

azelastine HCl and fluticasone propionate (Dymista) for seasonal allergic rhinitis and rhino-conjunctivitis

Patient group input submissions were received from the following patient groups. Those with permission to post are included in this document.
Asthma Society of Canada/National Asthma Patient Alliance — permission granted to post.

CADTH received patient group input for this review on or before January 5, 2015.

CADTH posts all patient input submissions to the Common Drug Review received on or after February 1, 2014 for which permission has been given by the submitter.

The views expressed in each submission are those of the submitting organization or individual; not necessarily the views of CADTH or of other organizations. While CADTH formats the patient input submissions for posting, it does not edit the content of the submissions.

CADTH does use reasonable care to prevent disclosure of personal information in posted material; however, it is ultimately the submitter's responsibility to ensure no personal information is included in the submission. The name of the submitting patient group and all conflict of interest information are included in the posted patient group submission; however, the name of the author, including the name of an individual patient or caregiver submitting the patient input, are not posted.

Asthma Society of Canada/National Asthma Patient Alliance

Section 1 — General Information

Name of the drug CADTH is reviewing and indication(s) of interest		Dymista (Azelastine HCl and fluticasone propionate) Seasonal allergic rhinitis and rhino-conjunctivitis
Name of the patient group		Asthma Society of Canada/National Asthma Patient Alliance
Name of the primary contact for this submission:		[redacted]
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Permission is granted to post this submission		Yes

1.1 Submitting Organization

The Asthma Society of Canada (ASC) is a national charitable volunteer-supported organization solely devoted to enhancing the quality of life and health for people living with asthma and associated allergies through education and research. The ASC has a 40-year reputation of providing health education services to consumers and health care professionals. The ASC offers evidence-based and age-appropriate asthma and allergy education, and disease management programs. Our *vision* at the ASC is to empower every child and adult with asthma in Canada to live an active and symptom-free life. Our *mission* is to be a balanced voice for asthma in Canada, advancing optimal self-management, prevention, research and health care.

We help patients to take control of their disease by providing credible and leading edge information and the guidance and education they need to live their lives symptom free. We lead and advocate for the best interests of Canadians with asthma and allergies through effective collaboration with policy-makers, researchers and health care providers. The *goals* established by our Board of Directors and operationalized in our three-year strategic plan are to: be the balanced voice in Canada advocating for patients with respiratory allergies and asthma; promote the best interest of asthma and respiratory allergy patients through effective collaboration with policy-makers, researchers and health care providers; educate and counsel patients to take control of their symptoms through effective self-management; engage in meaningful research to improve asthma prevention and management strategies; and be a respected role model and a well-managed association in the non-profit disease management sector in Canada.

The ASC established the National Asthma Patient Alliance (NAPA), a grass-roots patient group of the ASC in 2007 with an outreach to over 5000 allergy and asthma patients. It is overseen by an Executive Committee made up of volunteers from across Canada. It is the collective voice of patients with asthma and associated allergies sharing information and engaging in advocacy activities. Its programs include Team Asthma, Asthma Ambassadors and AsthmaPAC, the Patient Advocacy Committee.

1.2 Conflict of Interest Declarations

The ASC receives approximately 20 percent of its revenue from research-based pharmaceutical companies through unrestricted grants and occasional consulting fees and other fee for service contracts. In 2014, funds were received from GlaxoSmithKline, Novartis, AstraZeneca, Takeda, Merck, Pfizer, Paladin, Roche Canada, Boehringer-Ingelheim and Rx&D, the Canadian pharmaceutical industry association. We have never received funds or in-kind support, or promises of support, from Meda Pharmaceuticals.

Section 2 — Condition and Current Therapy Information

2.1 Information Gathering

Information for this Submission was attained through an on-line survey regarding respiratory allergies sent to NAPA members from across Canada in December 2014 (51 responses received). Additionally, our recent study of Severe Asthma Patients conducted in 2013, using one-on-one interviews with 24 people and an extensive on-line survey of patients, also yielded both qualitative and quantitative information relevant to this Submission. Lastly, relevant information from a 2013 patient survey regarding sublingual immunotherapy treatment for allergies has also been selectively included.

Regarding the 2014 surveyed population specifically, **87% of those surveyed suffer from seasonal allergies and have been diagnosed with seasonal allergic rhinitis**, also known as hay fever, by a medical professional. Almost 69% of them have symptoms all year round, but get noticeably worse during particular seasons. Approximately 23% experience symptoms only at specific times of the year, while 8% experience symptoms year round with no specific seasonal flare-ups. Almost all, 95%, have experienced season allergic rhinitis symptoms in the last year.

2.2 Impact of Condition on Patients

This survey clearly identified that there is a considerable impact on the quality of life day-to-day for patients with allergic rhinitis. When asked, patients indicated that as a result of allergic rhinitis 86% experienced troublesome symptoms, 77% experienced sleep disturbance and 74% felt that it impaired their daily activities, which included both leisure and sports. There was also a noticeable impact day-to-day on overall work productivity. **62% of those surveyed experienced a 50% or more reduction of work-place productivity. Half of those experience an 80% or greater reduction in productivity**.

In addition to lost work productivity, patients indicated that time spent visiting healthcare professionals for their allergic rhinitis provided an added day-to-day burden. In a normal year, patients would visit their Family Physician an average of four times per year, a nurse twice a year and a specialist twice a year. Half of all of those visits (two with their Family Physician, one with the nurse, and one with their specialist) are specifically due to their dissatisfaction with their current allergic rhinitis pharmacological treatment.

While symptoms persist year round, patients experience a greater number of symptom days in the spring months (April, May and June) and fall months (October, November and December) which also corresponded to the periods of time where they most use medication to treat their allergic rhinitis. The average patient experiences 29 allergic rhinitis episodes each year and each episode (described as a period of time when you experience symptoms continuously) lasts an average of 16 days.

Finally, patients were asked to include the severity (None, Mild, Moderate or Severe) of various symptoms when at their absolute worst. Symptoms surveyed included: itchy nose, nasal congestion, runny nose, sneezing, itchy eyes, watery eyes and eye redness. The symptom identified as most problematic was nasal congestion, with 100% of respondents indicating they experience moderate or severe symptoms. Additionally, 87% felt they had moderate or severe itchy eyes, and 84% felt they had moderate or severe runny nose. Results for additional moderate or severe symptoms included sneezing (78%), water eyes (78%), itchy nose (76%) and eye redness (65%).

2.3 Patients' Experiences With Current Therapy

It is estimated that between 20 and 25% of adults in Canada suffer from respiratory allergies. It is often manifested as allergic rhinitis (seasonal allergic rhinitis also commonly known as hay fever). Grass, tree and other plant pollens and some fungi trigger seasonal allergic rhinitis. All patients surveyed to inform this submission were screened to ensure that they had been physician-diagnosed with allergic rhinitis. Many also have asthma, though that is not considered specifically in this submission.

While schooled in trigger management and allergen avoidance, complete allergen avoidance is rarely possible for most Canadians with allergic rhinitis. Thus, medical treatment is required to function normally. Current treatments include prescription oral antihistamines, intranasal corticosteroids and antihistamine eye drops as well as many over-the counter products (in addition to asthma medications). Allergy shots performed in a physician's office are the current standard of care in Canada for people with more severe seasonal allergic rhinitis. A small number of people are also using sublingual immunotherapy (SLIT) though it is still not widely available.

Only 9% of those surveyed indicated that they were very satisfied with their current treatment and its effectiveness. Just over 41% indicated they were somewhat satisfied, leaving almost 50% as either somewhat unsatisfied or very unsatisfied with their current treatment.

A full 97% of respondents take medication to treat hay fever/seasonal allergic rhinitis. Currently, over 64% of respondents primarily use prescription nasal sprays (fluticasone propionate nasal spray), 34% primarily use tablets and 3% primarily use eye drops, however most reported using a combination of all of the above. Regarding subcutaneous immunotherapy, 22% reported receiving injections to treat their allergic rhinitis. Other medications taken include OTC products, nasal rinses and asthma medications.

Almost 58% take medications once per day, while 39% take medications twice a day. On average, they take medication for 31 days during a symptom episode. Almost all respondents re-use left-over medication across symptom episodes (95%).

Regarding specific brands of nasal sprays, 50% reported using Nasonex, 25% use Avamys, 8% use each of Flonase, Omnaris or Nasacort AQ.

Almost all respondents (93%) use some oral medications. The most commonly used are Acrivastine (Benadryl Allergy), Loratidine (Claritin), Tylenol Sinus, Aerius and Sudafed. Two-thirds of respondents also use eye drops to treat seasonal allergic rhinitis.

When asked why they take more than one medication at the same time, **58% said that one treatment does not treat all of their nasal symptoms effectively**. Almost 50% said that additional treatment was needed for eye symptoms. It was also indicated that nasal sprays do not act quickly enough and other medications are required for more immediate symptom relief.

Our most recent survey focused on the amount of time it takes before symptom improvement from current treatment options. Almost 43% reported that it took approximately three days; an additional 43% said it took 7 days and a further 14% indicated that it took 14 days for maximum symptom improvement using current treatment options.

Regarding side effects, only 31% claim no side effects from current medications. Side effects cited by others (from most prevalent to least): nosebleed (36%); drowsiness (33%), headache (31%); and bitter taste (28%). Other side effects included dry nose, throat irritation, asthma attacks; cough and mood changes. Side effects which patients would like to see reduced (again in order): asthma attacks, nosebleed, blocked nose, fatigue, cough, mood swings and headache.

From a previous patient survey (2013) hardships experienced by patients regarding their allergies include: financial burden of medications 74%; inability to get referral to an allergist 58%; lack of knowledge of family physicians 56%; missing work for medical appointments 37%; hospital visits and admissions 30%; changes to daily routine to accommodate treatment 16%.

2.4 Impact on Caregivers

From a previous survey of respiratory allergy sufferers (2013) the largest effect of allergies on caregivers is the need to change daily routines to accommodate (54%). Coping with medication side-effects negatively affected 50% of caregivers. 25% of caregivers routinely have had to take time off work to support the patient. Regarding treatments: 46% indicated that the financial burden of the disease was shared by the caregiver in an adverse way as well as time off work for medical appointments (27%) and for treatments performed in medical settings and physicians' offices (14%).

Section 3 — Information about the Drug Being Reviewed

3.1 Information Gathering

As above in Section 2.1.

3.2 What Are the Expectations for the New Drug or What Experiences Have Patients Had With the New Drug?

Patients, when told of the possibility of a new, faster-acting intranasal spray with almost immediate symptom results responded almost unanimously that they would be interested in trying it (98%). Ranked most important to them was quick relief from symptoms (time to feel better after first taking the medication as soon as within 30 minutes). Almost equally import was relief of all allergy symptoms including runny nose, sneezing, itchy/watery eyes, post nasal drip and nasal congestion. Safety ranked third, time required to achieve maximum relief ranked fourth and effects lasting more than one day was fifth.

Additional significance was attached to reduction in asthma attacks. Most patients understand their upper and lower airways diseases to be one disease rather than two and are hopeful that a new medication would not only reduce respiratory allergy symptoms but would lessen the possibility of asthma attacks. Patient needs were ranked from most important to least as: improving ability to breathe through their nose; reduce the number and severity of asthma attacks; reduce runny or blocked nose; reduce throat irritation; reduce persistent coughing; reduce itchy eyes, nose and throat; reduce watery eyes; reduce the loss of sense of taste and smell; improve sleep and reduce fatigue. It was also hoped that the new medication would result in less dependency upon rescue medications (short-acting relievers) for breathing problems.

Side effects that would not be tolerated included: severe sore throat, greater production of mucus, long-lasting swollen tongue or lip swelling, increased drowsiness and, of course, increase in number or severity of asthma attacks.

As indicated in Section 2.2 above, allergic rhinitis has a considerable impact on the quality of life. When asked, patients indicated that as a result of allergic rhinitis 86% experienced troublesome symptoms, 77% experienced sleep disturbance and three-quarters of them felt that it impaired their daily activities, which included leisure, sports and work. All expressed a desire to reduce the impact that allergic rhinitis has on their lives. They were also cognizant that, on average, 7 visits to health care professionals regarding their allergies were mostly due to their dissatisfaction with their current pharmacological treatments. It is universally hoped that this will improve with better, faster-acting, more comprehensive medications.

No patient surveyed had any experience with Dymista. We do not have access to patients who have been in clinical trials.