Minutes - National Drug Scheduling Advisory Committee Meeting – September 18, 2022

A virtual meeting of the National Drug Scheduling Advisory Committee (NDSAC) was held on Sunday, September 18, 2022.

Present:

NDSAC members:

Dr. Jason Kielly (Chair); Mr. Vaughn Chauvin; Dr. Michael Hamilton; Dr. Melanie Johnson; Mr. Husayn Kassam; Ms. Carole Kierstead; Mr. Kevin Pothier

Observers:

Ms. Joan Sayer – Consumers Association of Canada
Dr. Jason Fine - Natural and Non-prescription Health Products Directorate, Health Canada

NAPRA Staff – Committee Secretariat:

Sarah Marshall – Manager, Professional and Regulatory Affairs
Sarah ter Huurne - Pharmacy Practice Advisor
Krista Jajko – Project Specialist

Regrets:

Dr. Régis Vaillancourt

1.0 Call to order

1.1 Opening remarks

J. Kielly welcomed everyone and called the meeting to order at 10:02 a.m. (ET) on Sunday, September 18, 2022.

1.2 Roll call and declaration of quorum

J. Kielly noted the members in attendance and declared quorum.

1.3 Welcoming new members

J. Kielly welcomed Ms. Carole Kierstead as a new member of the NDSAC.

1.4 Conflict of interest declarations

J. Kielly called for conflict of interest declarations. None of the members had any conflicts of interest to declare. In addition to the request for conflict of interest declarations, participants and observers were reminded of the confidentiality policies in effect.

2.0 Approval of the agenda

A motion to approve the agenda as presented was put forward by M. Hamilton, seconded by V. Chauvin and approved by consensus.

3.0 Confirmation of approval of the minutes from the June 5, 2022 NDSAC meeting

The minutes of this meeting had previously been approved by the NDSAC members via email. A motion to formally confirm approval of the minutes from the NDSAC meeting of June 5,

2022 as posted on the NAPRA website was put forward by K. Pothier, seconded by M. Hamilton, and approved by consensus.

4.0 New Business

4.1 Request for Unscheduled status for brimonidine tartrate ophthalmic solution in concentrations up to and including 0.025%, used for the relief of redness of the eye due to minor eye irritations caused by environmental allergies, dryness and fatigue for adults of 18 years and older

The committee reviewed and considered the application for drug scheduling. The committee noted the new information (updated box label and post-market safety data) provided since the last review. No requests for interested party status and no comments via the alternate method of participation were received for this review.

At 11:15 a.m. on September 18, 2022, J. Kielly welcomed representatives from Bausch + Lomb: Andrea Linfield, Wendy Xiong, and John German. The Bausch + Lomb representatives gave a concise slide presentation to the committee, which was followed by a question-and-answer period.

The committee then discussed all the information previously provided to them for review and consideration, as well as the information received during the presentation and the subsequent question-and-answer period.

The committee observed that this active ingredient has only been available in the non-prescription environment in Canada for two months and considered this still a new non-prescription ingredient in Canada. In addition, there is limited global experience with this concentration of brimonidine, as well as with its sale as a non-prescription, self-selection product. The lower strength brimonidine product has only been available in two countries internationally: the United States since December 2017 and South Korea since January 2022. The committee appreciated the additional post-market safety information provided by the applicant, but noted that overall, there is still limited experience with non-prescription brimonidine tartrate 0.025% ophthalmic solution, particularly in the Canadian self-selection environment. While the limited available post-market safety data does not seem to have identified any significant safety signals to date, the experience with this ingredient, both at this concentration and in a non-prescription environment in Canada, is still new and patients would benefit from the availability of a pharmacist to promote safe and appropriate use of this new product.

Members discussed that while the product is indicated for relief of redness of the eye due to minor irritations caused by environmental allergies, dryness and fatigue, there can be many causes or conditions that may lead to eye redness. Therefore, a pharmacist should be available to assist with product selection and advise on place in therapy of this new non-prescription drug, amongst the many other potential ophthalmic treatments. It was also noted that redness of the eye can be a recurring condition and the product labelling does not provide information on appropriate retreatment intervals. Since clinical trials and limited post-market safety data to date

do not indicate the potential for serious safety concerns with recurrent use, it was agreed that while a pharmacist is not required to monitor recurring therapy in every case, they should be available to provide advice on symptom management and promote appropriate use.

The committee was also concerned about some aspects of the labelling. The committee reviewed the differences between the previously submitted labels and the updated labels provided, and noted the correction of a previous discrepancy regarding contact lens use. The potentially confusing information regarding the age range of the product (which was not tested in the label comprehension study) had not changed. Further, no new label comprehension studies were provided. The label comprehension study presented had been completed with older labelling. In addition, it did not address whether consumers could understand the appropriate age range, duration of therapy, or when to stop use and seek medical attention. Members agreed that a pharmacist should be available to reinforce these important messages for safe use of the product. Finally, the committee observed that some, but not all red flags indicating the need to consult a health practitioner were addressed in the labelling. They determined that the availability of a pharmacist to provide advice on the need for further assessment would be beneficial. Overall, members agreed that a pharmacist should be available to reinforce or expand on product labelling.

J. Kielly led the group in a review of the applicability of the National Drug Scheduling Factors. It was agreed that the following scheduling factors were applicable to brimonidine tartrate ophthalmic solution in concentrations up to and including 0.025%, used for the relief of redness of the eye due to minor eye irritations caused by environmental allergies, dryness and fatigue for adults of 18 years and older:

- #II-10, III-2, III-3, and III-5

The committee discussed the overall best fit for the scheduling of brimonidine tartrate ophthalmic solution in concentrations up to and including 0.025%, used for the relief of redness of the eye due to minor eye irritations caused by environmental allergies, dryness and fatigue for adults of 18 years and older. In consideration of the limited overall global post-market safety data, the particular lack of data in the Canadian self-selection environment, and potential patient needs in terms of product selection and labelling, the committee agreed that a pharmacist should be available to: assist patients with self-selection; reinforce the approved age range and duration of use; and clarify or expand on other potentially confusing information in the product labelling.

MOTION: It was moved by K. Pothier, seconded by H. Kassam to recommend that:

- Brimonidine tartrate ophthalmic solution in concentrations up to and including 0.025%, used for the relief of redness of the eye due to minor eye irritations caused by environmental allergies, dryness and fatigue for adults of 18 years and older remain in Schedule III.

- Brimonidine or its salts, **except** when sold as brimonidine tartrate ophthalmic solution in concentrations up to and including 0.025%, used for the relief of redness of the eye

due to minor eye irritations caused by environmental allergies, dryness and fatigue for adults of 18 years and older will remain in Schedule I (as per the Prescription Drug List)

Motion carried. All members agreed to the above noted motion.

This recommendation will be reported to the NAPRA Board of Directors.

5.0 Updates

5.1 Natural and Non-prescription Health Products Directorate

J. Fine provided an update on recent activities of the Natural and Non-prescription Health Products Directorate of Health Canada.

6.0 Next meeting

Tentatively scheduled for December 4-5, 2022

7.0 Adjournment

The meeting was adjourned at 2:50 p.m. (ET) on September 18, 2022.