

Minutes - National Drug Scheduling Advisory Committee Meeting – December 6, 2021

A virtual meeting of the National Drug Scheduling Advisory Committee (NDSAC) was held on Monday, December 6, 2021.

Present:

NDSAC members:

Dr. Deborah Kelly (Chair); Mr. Vaughn Chauvin; Dr. Michael Hamilton; Mr. Larry Hough; Dr. Melanie Johnson; Dr. Jason Kielly; Mr. Kevin Pothier; Dr. Régis Vaillancourt

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

Joseph McGraw - Pharmacy Student

1.0 Call to order

1.1 Opening remarks

D. Kelly welcomed everyone and called the meeting to order at 11:01 a.m. (ET) on Monday, December 6, 2021.

1.2 Roll call and declaration of quorum

D. Kelly noted the members in attendance and declared quorum.

1.3 Welcoming new members

D. Kelly welcomed Mr. Larry Hough and Dr. Régis Vaillancourt as new members of the NDSAC. D. Kelly also welcomed Dr. Jason Fine as the new observer from Health Canada and Mr. Joseph McGraw as a pharmacy student observer, under the supervision of S. ter Huurne.

1.4 Conflict of interest declarations

D. Kelly 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. Johnson, seconded by J. Kielly and approved by consensus.

3.0 Confirmation of approval of the minutes from the June 6 and 7, 2021 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

Minutes - National Drug Scheduling Advisory Committee Meeting – December 6, 2021

of June 6 and 7, 2021 as posted on the NAPRA website was put forward by V. Chauvin, 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 irritations caused by environmental allergies, dryness and fatigue for adults 18 years and older**

The committee reviewed and considered the application for drug scheduling. No requests for interested party status and no comments via the alternate method of participation were received for this review.

At 11:45 a.m. on December 6, 2021, D. Kelly welcomed representatives from Bausch Health: Krista Barbour, Rosemarie Childerhose, and Tibor Kapusy. The Bausch Health 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 is new to the non-prescription environment in Canada and has limited global experience as a non-prescription, self-selection product. The lower strength brimonidine product has only been available in one country internationally (the United States) since December 2017. Members noted that there is limited post-market safety data available for non-prescription brimonidine tartrate 0.025% ophthalmic solution. While the limited available post-market safety data does not seem to have identified any significant safety signals to date, the experience with the product is still new and patients would benefit from the availability of a pharmacist to promote safe and appropriate use of the 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.

It was also noted that redness of the eye can be a recurring condition. 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. There was potentially confusing information regarding the age range of the product that was not tested in the label comprehension study presented in the applicant's submission. Further,

Minutes - National Drug Scheduling Advisory Committee Meeting – December 6, 2021

the label comprehension study presented did not address whether consumers could understand the appropriate duration of therapy, and 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, especially given the limited post-market safety data about use of this product in a non-prescription setting.

D. Kelly 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 post-market safety data on non-prescription, self-selection use of this drug and other factors, 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 R. Vaillancourt 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 be granted Schedule III status, subject to the removal from the Prescription Drug List (PDL)
- 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.

Minutes - National Drug Scheduling Advisory Committee Meeting – December 6, 2021

5.0 Elections

5.1 Chair

S. ter Huurne called for nominations for the position of Chair of NDSAC. J. Kielly was nominated and agreed to put forth his candidacy for the position of Chair. No other nominations were received. M. Johnson moved to appoint J. Kielly as Chair, seconded by M. Hamilton and it was approved by consensus. J. Kielly was acclaimed as Chair of NDSAC.

5.2 Vice-Chair

S. ter Huurne called for nominations for the position of Vice-Chair of NDSAC. K. Pothier was nominated and agreed to put forth his candidacy for the position of Vice-Chair. No other nominations were received. L. Hough moved to appoint K. Pothier as Vice-Chair, seconded by V. Chauvin and it was approved by consensus. K. Pothier was acclaimed as Vice-Chair of NDSAC.

6.0 Updates

6.1 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.

7.0 Next meeting

Tentatively scheduled for March 6-7, 2022

8.0 Adjournment

The meeting was adjourned at 3:51 p.m. (ET) on December 6, 2021.