A meeting of the National Drug Scheduling Advisory Committee (NDSAC) was held on Sunday, December 1, 2019 at the Lord Elgin Hotel, Ottawa.

Present:

NDSAC members:

Ms. Kendra Townsend (Vice Chair); Dr. Murray Brown (via webconference); Dr. Melanie Johnson; Dr. Deborah Kelly; Dr. Jason Kielly (via webconference); Ms. Judy McPhee

Observers:

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

NAPRA Staff:

Sarah Marshall – Manager, Professional and Regulatory Affairs, Committee Secretary
Elizabeth Kozyra, Pharmacy Practice Specialist

Regrets:

Dr. Drena Dunford

1.0 Call to order

1.1 Opening remarks

K. Townsend welcomed everyone and called the meeting to order at 9:04 a.m. (ET) on Sunday, December 1, 2019. She led the committee in a moment of silence in memory of former NDSAC Chair, Dr. Tom Bailey, who passed away earlier this fall.

1.2 Roll call and declaration of quorum

K. Townsend noted the members in attendance and declared quorum.

1.3 Conflict of interest declarations

K. Townsend called for conflict of interest declarations. None of the members had any conflicts of interest to declare. Signed conflict of interest declarations were received in compliance with NDSAC requirements.

2.0 Approval of the agenda

A motion to approve the agenda as presented was put forward by M. Johnson, seconded by J. McPhee and approved by consensus.

3.0 Confirmation of approval of the minutes from the September 8, 2018 and the October 4-10, 2018 NDSAC meetings

The minutes of these meetings had previously been approved by the NDSAC members via email.

September 8, 2018

A motion to formally confirm approval of the minutes from the NDSAC meeting of September 8, 2018 as posted on the NAPRA website was put forward by M. Brown, seconded by D. Kelly and approved by consensus.

October 4-10, 2018 (email meeting)

A motion to formally confirm approval of the minutes from the NDSAC meeting of October 4-10, 2018 as posted on the NAPRA website was put forward by M. Johnson, seconded by D. Kelly and approved by consensus.

4.0 New Business

4.1 Request for Schedule III status for fluticasone propionate, when sold for the treatment of allergic rhinitis in a nasal spray that delivers 50mcg/spray for those 18 years of age and older, in package sizes containing up to 360 metered sprays

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 10:15 a.m., K. Townsend welcomed representatives from Glaxo Smith Kline Consumer Healthcare (GSK): Mr. Jeff Harris, Dr. Junaideen Fahumy and Ms. Stella Chan. The GSK representatives gave a concise slide presentation to the committee, which was followed by a question and answer period.

The committee then discussed 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 discussed the drug interaction that is known to occur between HIV medications and fluticasone propionate nasal spray. A newer HIV medication cobicistat, which is used in two of the first-line combination treatment options, has a similar interaction to ritonavir and is contraindicated with the use of fluticasone nasal spray in interaction references. The labelling included in the submission warned patients to ask a doctor or pharmacist before use if they 'take medicine for HIV infection (such as ritonavir)'. Although cobicistat was not mentioned, members agreed that the labelling was sufficient to prompt individuals to speak to a health professional prior to use if taking any HIV medication. Overall, the committee concluded that there are serious drug interactions which present a risk to patients, but that the labelling helped to mitigate some of this risk. However, it was agreed that a pharmacist must be available to answer questions about the interactions, assist patients in determining whether or not they can safely use the drug and reinforce the seriousness of the interaction with certain HIV medications.

In line with the assessment of this drug in 2016, the committee concurred that the availability of a pharmacist would help to promote safe and appropriate use of fluticasone propionate nasal spray. Some patients may benefit from receiving additional support from the pharmacist to help them choose the most appropriate treatment among the vast array of non-prescription products for allergic rhinitis. A pharmacist should be available to provide further information and education on how to appropriately prime, use and clean the nasal spray device to optimize treatment efficacy and reduce the risk of serious adverse reactions such as nasal septum perforation. A pharmacist should also be accessible to clarify information in the Drug Facts Table, which could be difficult to read for some patients, reinforce the age range for non-prescription use and highlight the need to stop use if symptoms do not improve within 7 days.

Since allergic rhinitis can be a persistent, recurring and/or chronic condition, it was agreed that a pharmacist must be available to reinforce the appropriate duration of use and monitor and refer patients who may need to use the drug longer than 3 months. The committee discussed the request to extend Schedule III status to package sizes of up to 360 metered sprays, in the context of the Health Canada approved duration of use for

the non-prescription setting of 3 months, after which consultation with a physician is recommended to determine if continued use is appropriate. There was discussion about how long 360 metered sprays would last, given the approved dosage for the non-prescription setting of 1-2 sprays of 50mcg in each nostril once daily. The committee concluded that a package size of 360 metered sprays aligned with the maximum approved dosage for non-prescription use for this drug.

Members discussed the importance to patient safety of ensuring product integrity when consumers purchase a larger package size, particularly given the potential intermittent nature of seasonal allergic rhinitis. Members noted that the expiry date of the medication must be clearly visible to consumers prior to purchase, including the earliest expiry date of any bottle when 3 bottles of 120 are combined in one package. Consumers must also be aware of the proper storage requirements in order to maintain product integrity when purchasing 360 metered sprays at one time. The expiry date location was not clear based on the labelling included in the submission and the mock-up product presented during the meeting. However, it was clarified during the meeting that it is a federal regulatory requirement that the expiry date be visible to consumers on the outer package (i.e. prior to purchase). Given this information, and the fact that the storage information was clearly indicated in the labelling presented, the committee agreed that pharmacist intervention was not required in all cases, but should be available. A pharmacist could contribute to appropriate use of the drug by reinforcing the importance of proper storage and verification of product expiry to ensure product integrity.

K. Townsend 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 fluticasone propionate, when sold for the treatment of allergic rhinitis in a nasal spray that delivers 50mcg/spray for those 18 years of age and older, in package sizes containing up to 360 metered sprays

- #I-6, III-3 and III-5

The committee discussed the overall best fit for the scheduling of this drug in package sizes of up to 360 metered sprays. Members agreed that pharmacist intervention is not required for package sizes that align with the maximum approved duration of use in a non-prescription setting. However, a pharmacist should be available to assist patients with self-selection, reinforce the importance of maintaining product integrity and clarify or expand on information in the product labelling as required for the patient's circumstances. Members agreed that package sizes of more than 360 metered sprays should be placed in Schedule II to provide additional opportunities to monitor and refer patients who may need to use the drug long-term.

MOTION: It was moved by J. McPhee, seconded by D. Kelly to recommend that:

Fluticasone propionate, when sold for the treatment of allergic rhinitis in a nasal spray that delivers 50 mcg/spray for those 18 years of age and older, in package sizes containing no more than 360 metered sprays, be granted Schedule III status.

and

Fluticasone propionate, when sold for the treatment of allergic rhinitis in a nasal spray that delivers 50 mcg/spray for those 18 years of age and older, in package sizes containing more than 360 metered sprays, be granted Schedule II status

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

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

5.0 Election of Chair and Vice Chair

Chair: K. Townsend called for nominations for the position of Chair of NDSAC. D. Kelly was nominated and agreed to put forth her candidacy for the position of Chair. No other nominations were received and D. Kelly was acclaimed as Chair of NDSAC.

Vice Chair: K. Townsend called for nominations for the position of Vice Chair of NDSAC. J. Kielly was nominated and agreed to put forth his candidacy for the position of Vice Chair. No other nominations were received and J. Kielly was acclaimed as Vice Chair of NDSAC.

The committee and NAPRA staff expressed their appreciation to non-returning members for their hard work and commitment to the committee over the past 6 years. NAPRA will follow its usual process to recruit additional committee members as required.

6.0 Updates

6.1 Natural and Non-prescription Health Products Directorate

S. Ghimire provided an update on the activities of the Natural and Non-Prescription Health Products Directorate and Health Canada. The Directorate continues to work on the Plain Language Labelling Initiative and is collaborating with licence holders regarding compliance activities. Health Canada is working on modernizing the *Food and Drug Regulations*, and some of these changes may impact how non-prescription drugs will be regulated in the future.

6.2 NAPRA Strategic Plan 2019-2023

S. Marshall provided an update on progress towards the NAPRA Strategic Plan 2019-2023, including plans to continue moving forward on the review of the NDS program in 2020. S. Marshall reminded NDSAC members of the recent update to NAPRA's *Policy on Natural Health Products* and explained that information about this change was posted to the NAPRA website on November 29, 2019.

7.0 Next meeting

Tentatively scheduled for March 8-9, 2020.

8.0 Adjournment

The meeting was adjourned at 12:30 p.m (ET).