Minutes - National Drug Scheduling Advisory Committee Meeting – June 2, 2024

A virtual meeting of the National Drug Scheduling Advisory Committee (NDSAC) was held on Sunday, June 2, 2024.

Present:

NDSAC members:

Jason Kielly (Chair); Vaughn Chauvin; Michael Hamilton; Certina Ho; Husayn Kassam; Carole Kierstead; Kevin Pothier; Marjorie Rempel Friesen

Observers:

Joan Sayer – Consumers Association of Canada
Michel Ntemgwa - Natural and Non-prescription Health Products Directorate, Health Canada
Kevin Bernardo – Marketed Health Products Directorate, Health Canada

NAPRA Staff – Committee Secretariat:

Sarah Marshall – Manager, Professional and Regulatory Affairs
Sarah ter Huurne – Senior Pharmacist Specialist, Professional and Regulatory Affairs
Krista Jajko – Project and Policy Advisor, Professional and Regulatory Affairs

1.0 Call to order

1.1 Opening remarks

J. Kielly welcomed everyone and called the meeting to order at 11:02 a.m. (ET) on Sunday, June 2, 2024.

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 Certina Ho 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.

1.5 Confidentiality Reminder

J. Kielly reminded participants and observers 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 December 3-4, 2023 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 December 3-4, 2023, as posted on the NAPRA website, was put forward by C. Kierstead, seconded by V. Chauvin, and approved by consensus.

4.0 New Business

4.1 Request for Unscheduled status for desloratadine and its salts and preparations in products marketed for pediatric use, age 2 to 11 years, in package sizes containing no more than 70 mg of desloratadine

and

Schedule III status for desloratadine and its salts and preparations in products marketed for pediatric use, age 2 to 11 years, in package sizes containing greater than 70 mg of desloratadine.

The committee reviewed and considered the application for drug scheduling, as well as additional information submitted through the alternate method of participation. No requests for interested party status were received for this review.

At 11:47 a.m. (ET) on June 2, 2024, J. Kielly welcomed representatives from Bayer: Paul Keith, Chris Sans, and Joseph Chan. The Bayer 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 been available for use in children without a prescription in Canada for many years. They discussed the safety profile of desloratadine in children. The committee noted that many references cite low incidence of adverse effects and a wide margin of safety between therapeutic and toxic doses for desloratadine, including in children. Although serious adverse effects have been reported very rarely, it was agreed that this did not alter the overall safety profile given the extremely low incidence, the limited number of reports, and the fact that causality had not been confirmed. Therefore, the committee agreed that desloratadine had an overall positive safety profile. Additionally, it was noted that current guidelines recommend second generation antihistamines as first line treatment options for children with allergic rhinitis and chronic urticaria, due to their efficacy and strong safety profile in this population. However, the committee also identified the potential for a pharmacist to contribute to safe and appropriate use of the drug with regards to appropriate product selection and reinforcing product labelling.

While the literature indicates that allergic rhinitis is considered rare in children under the age of six (6) years, and some references outline the importance of establishing an initial diagnosis in this population, the committee agreed that the risks are low if an inappropriate assessment is made, given the strong safety profile of this drug. However, it may be difficult for parents to choose the most appropriate product among the vast array of non-prescription products available for allergic rhinitis or urticaria. Thus, a pharmacist should be available to assist with product selection when required.

A consumer survey provided by Bayer suggested that, despite the majority of respondents reporting comfort understanding product information, there was a proportion of respondents who could benefit from a pharmacist to reinforce product labelling, especially considering the limitations of the survey which included: the self-reported nature of the survey, the small sample size, and the potential bias towards higher health literacy respondents since the survey was conducted online in English. The committee concluded that the availability of a pharmacist to reinforce product labelling could contribute to the safe and appropriate use of the drug, particularly to provide advice on appropriate dosing ranges and measurement of accurate doses.

Members noted that allergic rhinitis and chronic urticaria are often persistent, recurrent or chronic conditions for many individuals, and that non-prescription desloratadine for children aged 2 to 11 years of age is only approved for a duration of 14 days, since long-term safety and efficacy in this age range has not been demonstrated according to the product monograph. The availability of a pharmacist could help parents and caregivers whose children are using the drug for a longer duration to determine if it is the most appropriate therapy for their circumstances, educate on the benefits and risks of off-label use, and assist in optimally managing their condition.

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 desloratadine and its salts and preparations in products labelled for use in children aged 2 to 11 years:

- #III-3 and III-5

The committee discussed the overall best fit for the scheduling of desloratadine and its salts and preparations in products labelled for use in children aged 2 to 11 years. Members discussed the balance between reasonable consumer access to this safe treatment option and maintaining pharmacist availability to provide advice in this potentially more vulnerable pediatric population. Although desloratadine has a strong safety profile in children aged 2 to 11 years, there is limited data on long-term use in this age group and it is only approved for short-term use in the non-prescription setting. Therefore, the committee determined that restricting package sizes that exceed the maximum Health Canada approved dose and duration of use to the pharmacy setting would mean that a pharmacist is available and could provide advice on the appropriate management of allergic rhinitis or chronic urticaria, and the benefits and risks of off-label, long-term use.

MOTION: It was moved by V. Chauvin, seconded by H. Kassam to recommend that:

- Desloratadine and its salts and preparations in products labelled for use in children aged 2 to 11 years, in package sizes containing greater than 35mg of desloratadine, remain in Schedule III

- Desloratadine and its salts and preparations in products labelled for use in children aged 2 to 11 years, in package sizes containing no more than 35mg of desloratadine, be granted Unscheduled status

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

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

For clarity, desloratadine and its salts and preparations, in products labelled for use in individuals 12 years of age and older will remain Unscheduled.

5.0 Elections

5.1 Election of Chair

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

5.2 Election of Vice-Chair

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

6.0 Updates

6.1 Natural and Non-prescription Health Products Directorate

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

6.2 Marketed Health Product Directorate

M. Ntemgwa provided an update on recent activities of the Marketed Health Products Directorate of Health Canada, on behalf of K. Bernardo.

6.3 NDS Modernization Product

K. Jajko provided an update on the NDS modernization project.

7.0 Next meeting

Tentatively scheduled for September 15-16, 2024.

8.0 Adjournment

The meeting was adjourned at 2:36 p.m. (ET) on June 2, 2024.