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

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

Present:

NDSAC members:

Vaughn Chauvin (Chair); Nicolas DesAulniers; Michael Hamilton; Certina Ho; Husayn Kassam; Carole Kierstead; Jaclyn McCarville; 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

V. Chauvin welcomed everyone and called the meeting to order at 10:05 a.m. (ET) on Monday, December 2, 2024.

1.2 Roll call and declaration of quorum

V. Chauvin noted the members in attendance and declared quorum.

1.3 Welcoming new members

V. Chauvin welcomed Nicolas DesAulniers and Jaclyn McCarville as new members of the NDSAC.

1.4 Conflict of interest declarations

V. Chauvin called for conflict-of-interest declarations. None of the members had any conflicts of interest to declare.

1.5 Confidentiality Reminder

V. Chauvin 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 C. Kierstead, seconded by M. Hamilton, and approved by consensus.

3.0 Confirmation of approval of the minutes from the September 15, 2024 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 September

15, 2024, as posted on the NAPRA website, was put forward by C. Ho, seconded by H. Kassam, and approved by consensus.

4.0 New Business

4.1 Request for Unscheduled status for cetirizine or its salts, in concentrations of 10 mg equivalent to 8.5 mg or less of cetirizine base per dosage unit, in products marketed for pediatric use (under 12 years of age)

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 10:46 a.m. (ET) on December 2, 2024, V. Chauvin welcomed representatives from Kenvue: Tammi Schaeffer, Hilary Orr, and Sona Arslan. The Kenvue 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 cetirizine in children. While somnolence has been reported with cetirizine use, the committee noted that many references cite this as a low risk in children and cite a low overall incidence of adverse effects and a wide margin of safety between therapeutic and toxic doses, 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 and the fact that causality had not been confirmed. Therefore, the committee agreed that cetirizine 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 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 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 caregivers to choose the most appropriate product among the vast array of non-prescription products available for allergic rhinitis or urticaria. Thus, the availability of a pharmacist would contribute to appropriate use by providing assistance with product selection when required.

The committee noted that no label comprehension study was provided in the submission to support that caregivers understand the product labelling. The committee discussed the potential

confusing information on the product labelling, including different dosing regimens and overlap in dosing for children 6 years of age. The committee concluded that, given the strong safety profile of the drug, pharmacist intervention was not required, but 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 regimens and dosing ranges.

Members noted that non-prescription cetirizine for children aged 2 to 11 years of age is only approved for a duration of 14 days unless "directed by a physician". However, allergic rhinitis and urticaria are often persistent, recurrent, or chronic conditions for many individuals, and thus the availability of a pharmacist could help 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, long-term use, and assist in optimally managing their condition.

V. Chauvin 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 cetirizine 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 cetirizine 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, assist with product selection and reinforce labelling information in this potentially more vulnerable pediatric population. Although cetirizine has a strong safety profile in children aged 2 to 11 years, 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 for the non-prescription setting to a Schedule III environment would mean that a pharmacist is available and could provide advice on the appropriate management of allergic rhinitis or 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:

- Cetirizine or its salts, when sold in concentrations of 8.5 mg or less of cetirizine base per unit dose, in products labelled for use in children aged 2 to 11 years, in package sizes containing greater than 119 mg of cetirizine base, remain in Schedule III

- Cetirizine or its salts, when sold in concentrations of 8.5 mg or less of cetirizine base per unit dose, in products labelled for use in children aged 2 to 11 years, in package sizes containing no more than 119 mg of cetirizine base, be granted Unscheduled status

- Cetirizine or its salts, when sold in concentrations of 8.5 mg or less of cetirizine base per unit dose, in products labelled for use in individuals 12 years of age and older, remain Unscheduled

  ***Note: 8.5 mg of cetirizine base is approximately equivalent to 10 mg of cetirizine hydrochloride*

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

M. Ntemgwa shared that there were no new updates from the Natural and Non-prescription Health Products Directorate of Health Canada.

5.2 Marketed Health Products Directorate

K. Bernardo shared that there were no new updates from Marketed Health Products Directorate of Health Canada.

6.0 Next meeting

Tentatively scheduled for March 23-24, 2025.

7.0 Adjournment

The meeting was adjourned at 1:31 p.m. (ET) on December 2, 2024.