

Minutes - National Drug Scheduling Advisory Committee Meeting – March 5, 2023

A virtual meeting of the National Drug Scheduling Advisory Committee (NDSAC) was held on Sunday, March 5, 2023.

Present:

NDSAC members:

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

Observers:

Joan Sayer – Consumers Association of Canada

Michel Ntemgwa - Natural and Non-prescription Health Products Directorate, Health Canada

Pharmacy Student Observer:

Bethany Oldford, pharmacy student under the supervision of J. Kielly

NAPRA Staff – Committee Secretariat:

Sarah Marshall – Manager, Professional and Regulatory Affairs

Sarah ter Huurne - Pharmacy Practice Advisor

Krista Jajko – Project Specialist

Regrets:

Kevin Bernardo – Marketed Health Products Directorate, Health Canada

1.0 Call to order

1.1 Opening remarks

J. Kielly welcomed everyone and called the meeting to order at 10:31 a.m. (ET) on Sunday, March 5, 2023.

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 Marjorie Rempel Friesen as a new member of the NDSAC. J. Kielly also welcomed Michel Ntemgwa as a returning observer from Health Canada and Bethany Oldford as a pharmacy student observer, under his supervision.

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

3.0 Confirmation of approval of the minutes from the September 18, 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 September 18, 2022 as posted on the NAPRA website was put forward by M. Hamilton, seconded by C. Kierstead, and approved by consensus.

4.0 New Business

4.1 Request for Unscheduled status for loratadine and its salts and preparations in products marketed for pediatric use in children aged 2 to 11 years

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 11:30 a.m. on March 5, 2023, 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 for many years, both in Canada and globally. They discussed the overall positive safety profile, noting that many references cite low incidence of adverse effects and a wide margin of safety between therapeutic and toxic doses. It was noted that current guidelines recommend second generation antihistamines as first line treatment options for allergic rhinitis and chronic urticaria, due to their efficacy and strong safety profile. However, the committee also identified the potential for a pharmacist to contribute to safe and appropriate use of the drug with regards to appropriate self-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 was determined that product selection may cause confusion due to the fact that currently available product formulations do not all have the same indications. In addition, 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.

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The committee agreed that additional clarification of labelling information about the approved indications for each formulation, and appropriate dosing with regards to age and weight, could be beneficial. Further, 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 self-reported nature of the survey and 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 labeling could contribute to the safe and appropriate use of the drug.

Members noted that seasonal allergic rhinitis and chronic urticaria are often persistent, recurrent or chronic conditions for many individuals, and that non-prescription loratadine 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 loratadine 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 loratadine 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 loratadine 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 seasonal allergic rhinitis or chronic urticaria, and the benefits and risks of off-label, long-term use.

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

- Loratadine and its salts and preparations in products labelled for use in children aged 2 to 11 years, in package sizes containing greater than 140mg of loratadine, remain in Schedule III

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- Loratadine and its salts and preparations in products labelled for use in children aged 2 to 11 years, in package sizes containing no more than 140mg of loratadine, be granted Unscheduled status
- Loratadine and its salts and preparations, in products labelled for use in individuals 12 years of age and older, remain Unscheduled

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

5.2 Marketed Health Product Directorate

K. Bernardo was not able to attend the meeting, therefore no update was provided on recent activities of the Marketed Health Products Directorate of Health Canada.

5.3 NDSAC terms and appointments

S. ter Huurne provided an update on current terms and upcoming replacement needs for the NDSAC.

5.4 NDS Modernization Product

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

6.0 Next meeting

Tentatively scheduled for June 11-12, 2023.

7.0 Adjournment

The meeting was adjourned at 4:05 p.m. (ET) on March 5, 2023.