Minutes - National Drug Scheduling Advisory Committee Meeting – September 15, 2024

A meeting of the National Drug Scheduling Advisory Committee (NDSAC) was held on Sunday, September 15, 2024, at the Lord Elgin Hotel, Ottawa.

Present:

NDSAC members:

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

Observers:

Joan Sayer – Consumers Association of Canada (virtual attendance)
Michel Ntemgwa - Natural and Non-prescription Health Products Directorate, Health Canada

Pharmacy Student Observer:

Samantha Situ-Pham, pharmacy student under the supervision of J. Kielly (virtual attendance)

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 (virtual attendance)

Regrets:

Kevin Bernardo – Marketed Health Products Directorate, Health Canada

1.0 Call to order

1.1 Opening remarks

V. Chauvin welcomed everyone and called the meeting to order at 9:02 a.m. (ET) on Sunday, September 15, 2024. V. Chauvin welcomed Samantha Situ-Pham as a pharmacy student observer, under the supervision of J. Kielly.

1.2 Roll call and declaration of quorum

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

1.3 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 M. Hamilton, seconded by J. Kielly, and approved by consensus.

3.0 Confirmation of approval of the minutes from the June 2, 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 June 2, 2024, as posted on the NAPRA website, was put forward by J. Kielly, seconded by M. Rempel Friesen, and approved by consensus.

4.0 New Business

4.1 Request for Schedule II status for nirsevimab

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 9:46 a.m. (ET) on September 15, 2024, V. Chauvin welcomed representatives from Sanofi (virtual attendance): Meenal Joshi, Meagan Bardan, and Brooke Pathania. The Sanofi 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.

Nirsevimab is indicated for the prevention of Respiratory Syncytial Virus (RSV) lower respiratory tract disease in neonates and infants during their first RSV season and children up to 24 months of age who remain vulnerable to severe RSV disease through their second RSV season, which may include but is not limited to children with: chronic lung disease of prematurity (CLD), hemodynamically significant congenital heart disease (CHD), immunocompromised states, Down syndrome, cystic fibrosis, neuromuscular disease, and/or congenital airway anomalies. The only contraindication is for patients with a known hypersensitivity to any component of the product. As a preventative therapy, a diagnosis is not required to confirm the need for the drug. However, the committee agreed that while a caregiver could identify the initial need for nirsevimab for their child in the first RSV season based on the product monograph and available public health recommendations, and some aspects related to the need for the drug in the second RSV season, a regulated health professional, such as a pharmacist, is required to confirm the need for, and appropriateness of, the drug for that specific child. The pharmacist, or other regulated health professional, is required to assess the patient and confirm whether nirsevimab is appropriate based on age, contraindications, previous RSV infection status, other RSV preventative measures taken (e.g., pregnant individuals who received an RSV vaccination at the appropriate time prior to the infant's birth), and risk factors for continued vulnerability in season two. In addition, a pharmacist or other regulated health professional is required to help with product selection, considering the new and evolving RSV preventative options, as well as to ensure the correct dose and timing of administration of nirsevimab.

Re-treatment with nirsevimab is indicated and recommended for children who remain vulnerable to RSV in their second RSV season. For the reasons noted above, a pharmacist or other regulated health professional is required to ensure that re-treatment in the second RSV season is appropriate. Additionally, a pharmacist or other regulated health professional should be involved in re-treatments to monitor for, and educate caregivers about, potential adverse reactions.

The committee observed that this active ingredient is a new medicinal ingredient in Canada and has limited global experience. There are currently no other drugs in the same class available in a non-prescription environment in Canada. Nirsevimab is currently available in other international jurisdictions but has not been used for more than one RSV season in any jurisdiction globally. As such, there is limited post-market safety data available for nirsevimab. 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/caregivers require the involvement of a pharmacist or other regulated health professional to ensure safe and appropriate use of the new product.

Nirsevimab is an intramuscular injection that must be administered by a regulated health professional. As such, the product labelling is not designed for the public, but rather for health professionals. Therefore, the labelling would not provide caregivers with all of the information they need to know if their child is receiving this drug. The committee agreed that a pharmacist is required to ensure that the caregiver will have the drug administered by a health professional and to expand on the labelling information to educate caregivers regarding safe and appropriate use, dosing and storage, as well as possible adverse reactions and monitoring requirements.

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 nirsevimab:

- #I-8, II-1, II-2, II-4, II-6, II-9, II-10, III-2, and III-5

The committee discussed the overall best fit for the scheduling of nirsevimab. Members discussed the current burden of RSV infections on individuals and the healthcare system and the importance of reducing access barriers that a prescription requirement might present. Further, the committee agreed that a Schedule I placement was not required based on the application of scheduling factors, as it would not mitigate the concerns of the only applicable Schedule I factor related to uncertainty due to limited post-market experience. It was agreed that a Schedule III or Unscheduled environment would not be appropriate as the drug requires administration by a health professional, requires health professional intervention to determine whether the drug is appropriate for the particular child, and the labelling is not designed for self-selection or self-medication and thus additional education for the caregiver is required. Therefore, the committee determined that a Schedule II placement is important to ensure safe and appropriate use of nirsevimab.

MOTION: It was moved by J. Kielly, seconded by C. Ho to recommend that:

- Nirsevimab 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 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

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

6.0 Next meeting

Tentatively scheduled for December 1-2, 2024.

7.0 Adjournment

The meeting was adjourned at 2:04 p.m. (ET) on September 15, 2024.