Minutes - National Drug Scheduling Advisory Committee Meeting – June 5, 2022

A meeting of the National Drug Scheduling Advisory Committee (NDSAC) was held on Sunday, June 5, 2022 at the Lord Elgin Hotel, Ottawa.

Present:

NDSAC members:

Dr. Jason Kielly (Chair); Mr. Vaughn Chauvin (virtual attendance); Dr. Michael Hamilton (virtual attendance); Mr. Husayn Kassam; Mr. Kevin Pothier; Dr. Régis Vaillancourt

Observers:

Ms. Joan Sayer – Consumers Association of Canada (virtual attendance)
Dr. Jason Fine - Natural and Non-prescription Health Products Directorate, Health Canada (virtual attendance)

NAPRA Staff – Committee Secretariat:

Sarah Marshall – Manager, Professional and Regulatory Affairs
Sarah ter Huurne - Pharmacy Practice Advisor
Jocelyn Bonti-Ankomah - Pharmacy Student (virtual attendance)

Regrets:

Dr. Melanie Johnson

1.0 Call to order

1.1 Opening remarks

J. Kielly welcomed everyone and called the meeting to order at 9:03 a.m. (ET) on Sunday, June 5, 2022.

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 Husayn Kassam as a new member of the NDSAC. J. Kielly also welcomed Jocelyn Bonti-Ankomah as a pharmacy student observer, under the supervision of S. ter Huurne.

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. In addition to the request for conflict of interest declarations, participants and observers were reminded 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 R. Vaillancourt and approved by consensus.

3.0 Confirmation of approval of the minutes from the December 6, 2021 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 6, 2021 as posted on the NAPRA website was put forward by R. Vaillancourt, seconded by M. Hamilton, and approved by consensus.

4.0 New Business

4.1 Request for Unscheduled status for diclofenac diethylamine when sold as a single medicinal ingredient for topical use on the skin in a concentration of 2.32% or less for not more than 7 days

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. on June 5, 2022, J. Kielly welcomed representatives from GlaxoSmithKline Consumer Healthcare (GSK): Anela Lihic Haveric, Geoffrey Saroea, and Heather Goulding. The GSK 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 noted that while the product is only indicated for short-term use, the drug is used off-label for persistent, recurrent or chronic pain, as supported by the literature. The committee reviewed and appreciated the additional data from the literature and post-market safety reports since the last review of this drug, which support a low risk to patient safety if the drug is used long-term. Therefore, it was agreed that a pharmacist is not required to monitor chronic or recurrent therapy in every case. Nevertheless, since the drug is only indicated for short-term use, the availability of a pharmacist to provide advice on the benefits and risks of off-label use and the various treatment options for long-term pain could help promote appropriate therapy.

The committee discussed concerns related to the potential for product selection to cause confusion. They determined that a pharmacist could help explain the similarities and differences between the numerous topical diclofenac line extensions and the potential for confusion between different age ranges and directions for use of line extensions. Further, a pharmacist could help a patient choose the safest and most appropriate therapy for their particular circumstances amongst the many topical and oral therapies available for pain.

Members were in agreement that a pharmacist could help to reinforce or expand on product labelling, including educating patients on appropriate dosing and use of the unique dosing card in this product, reinforcing the appropriate age range and clarifying other potentially confusing information in the labelling. Since the literature and post-

market data support a low risk of systemic absorption and low risk to patient safety of use in individuals over 65, the committee agreed that a pharmacist was not required to explain the labelling, but could contribute to safe and appropriate use of the drug.

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 diclofenac diethylamine when sold as a single medicinal ingredient for topical use on the skin in a concentration of 2.32% for not more than 7 days:

- #III-3 and III-5

The committee discussed the overall best fit for the scheduling of diclofenac diethylamine when sold as a single medicinal ingredient for topical use on the skin in a concentration of 2.32% for not more than 7 days. The committee considered the need to balance access to this safe treatment option with maintaining pharmacist availability to provide advice on the safest and most appropriate therapy, assist with product selection, and reinforce labelling information, particularly for patients with persistent, chronic or recurring pain. While the literature and available post-market safety data support a low risk to patients using the drug long term, the drug is only approved for short-term use in the non-prescription environment. Therefore, the committee determined that it would be beneficial to have a pharmacist available to promote appropriate use and educate on the benefits and risks of off-label use for individuals purchasing large amounts. The committee agreed that the maximum quantity of diclofenac diethylamine in a package available in an Unscheduled environment should be proportionate to the amount required for a few possible usages per year of the approved daily dosage and duration of use.

MOTION: It was moved by R. Vaillancourt, seconded by M. Hamilton to recommend that:

- Diclofenac diethylamine – for human use - when sold as a single medicinal ingredient for topical use on the skin in concentrations greater than 1.16% and less than or equal to 2.32% for not more than 7 days - in package sizes containing greater than 2.6g of diclofenac diethylamine be granted Schedule III status

- Diclofenac diethylamine – for human use - when sold as a single medicinal ingredient for topical use on the skin in concentrations greater than 1.16% and less than or equal to 2.32% for not more than 7 days - in package sizes containing no more than 2.6g of diclofenac diethylamine be granted Unscheduled status

- Diclofenac diethylamine – for human use - when sold as a single medicinal ingredient for topical use on the skin in concentrations of not more than 1.16% for not more than 7 days 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

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

6.0 Next meeting

Tentatively scheduled for September 18-19, 2022

7.0 Adjournment

The meeting was adjourned at 2:14 p.m. (ET) on June 5, 2022.