Minutes - National Drug Scheduling Advisory Committee Meeting - June 6-7, 2021

A virtual meeting of the National Drug Scheduling Advisory Committee (NDSAC) was held on Sunday, June 6, 2021 and Monday, June 7, 2021.

Present:

NDSAC members:

Dr. Deborah Kelly (Chair); Dr. Murray Brown; Mr. Vaughn Chauvin; Dr. Drena Dunford; Dr. Michael Hamilton; Dr. Melanie Johnson; Dr. Jason Kielly; Mr. Kevin Pothier;

Observers:

Ms. Joan Sayer – Consumers Association of Canada
Dr. Michel Ntemgwa - Natural and Non-prescription Health Products Directorate, Health Canada

Pharmacy Student Observer:

Ms. Rebecca Spurrell, 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

1.0 Call to order

1.1 Opening remarks

D. Kelly welcomed everyone and called the meeting to order at 11:03 a.m. (ET) on Sunday, June 6, 2021. The meeting ended at 4:54 p.m. (ET) on June 6, 2021 and resumed again at 11:03 a.m. (ET) on June 7, 2021.

1.2 Roll call and declaration of quorum

D. Kelly noted the members in attendance and declared quorum.

1.3 Welcoming new members

D. Kelly welcomed Mr. Vaughn Chauvin and Dr. Michael Hamilton as new members of the NDSAC. D. Kelly also welcomed Dr. Michel Ntemgwa as the new observer from Health Canada and Ms. Rebecca Spurrell as a pharmacy student observer, under the supervision of J. Kielly.

1.4 Conflict of interest declarations

D. Kelly called for conflict of interest declarations. None of the members had any conflicts of interest to declare for either review. 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 M. Brown, seconded by M. Johnson and approved by consensus.

3.0 Confirmation of approval of the minutes from the June 15 and 18, 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 June 15 and 18, 2020 as posted on the NAPRA website was put forward by D. Dunford, seconded by K. Pothier, and approved by consensus.

4.0 New Business

4.1 Request for Unscheduled status for bisacodyl 5mg tablets in all package sizes

The committee reviewed and considered the application for drug scheduling, as well as additional information submitted through the Interested Party process and the Alternate Method of Participation. Bayer Inc. Consumer Health was granted Interested Party status. Six interrogatories were completed during the interrogatory process. There was one submission of information by the Interested Party. The committee received one submission via the alternate method of participation.

At 11:45 a.m. on June 6, 2021, D. Kelly welcomed representatives from Sanofi: Dr. Robert Lange, Ms. Christina Moccia, and Dr. Giuseppa Gennaro. 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.

Members were concerned with the fact that the information presented and consulted demonstrated that there is potential for misuse and abuse of stimulant laxatives, including bisacodyl. The consequences of such misuse or abuse can be serious. While the committee noted that individuals with eating disorders seem to make up the majority of those that misuse or abuse stimulant laxatives, there are other groups that also misuse and abuse stimulant laxatives (e.g. The literature also noted the potential for misuse in individuals who are generally middle-aged or older who begin using when constipated but continue to overuse, individuals engaged in certain types of athletic training and surreptitious laxative abusers who use the drugs to cause factitious diarrhea.) A pharmacist should be available to provide support and assistance to patients who may be more at risk of abuse and misuse of bisacodyl.

It was noted that while the product is only indicated for short-term occasional use, constipation is often persistent, recurrent or chronic for many individuals and off-label, long-term use of stimulant laxatives has been reported. Although stimulant laxatives are considered safe to use long-term by some guidelines, others recommend against their long-term use and clinical trials beyond 4 weeks' duration are lacking. Further, stimulant laxatives are generally not considered first line therapy for the treatment of constipation.

A pharmacist should be available to provide advice on appropriate management of long-term constipation.

The committee was also concerned about the quality of the current labelling and noted that the applicant did not provide a label comprehension study for the current labelling. In addition, the label comprehension study completed on the proposed labels only addressed the use of the product and did not confirm understanding of any other aspects such as dosing, duration, warnings and drug interactions. While the labelling contains some information regarding red flags (or alarm symptoms), it does not include all the red flags that may be of concern with constipation. Drug interactions were missing from the current outer labelling and even if added as proposed, the terminology could be confusing to some patients. The committee therefore agreed that a pharmacist should be available to help reinforce and expand on the current product labelling.

D. Kelly 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 bisacodyl 5mg oral tablets:

- #II-5, III-3, III-4, III-5

The committee discussed the overall best fit for the scheduling of bisacodyl 5mg oral tablets. The committee discussed the balance between consumer access to the product and maintaining pharmacist oversight on product usage to address concerns with the potential for long-term use, misuse, and abuse. Restricting package sizes that exceed the maximum Health Canada approved dose and duration of use to the pharmacy setting would ensure that a pharmacist is available to monitor for patients potentially using the drug inappropriately, to provide advice on the appropriate management of long-term constipation and to assist with the identification of red flags that may indicate the need for further assessment, particularly with long-term use.

MOTION: It was moved by J. Kielly, seconded by V. Chauvin to recommend that:

- Bisacodyl, when sold in strengths of 5mg or less per oral dosage unit, in package sizes containing no more than 105 mg of bisacodyl, be granted Unscheduled Status

- Bisacodyl, when sold in strengths of 10 mg or less per rectal dosage unit/suppository, in package sizes containing no more than 50 mg of bisacodyl, remain Unscheduled

- Bisacodyl and its salts, **except** when sold in strengths of 5 mg or less per oral dosage unit in package sizes containing no more than 105mg of bisacodyl and **except** when sold in strengths of 10mg or less per rectal dosage unit/suppository in package sizes containing no more than 50mg of bisacodyl, remain in Schedule III

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

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

4.2 Request for Schedule II status for non-live recombinant herpes zoster vaccine

The committee reviewed and considered the application for drug scheduling, as well as additional information submitted through the Interested Party process and the Alternate Method of Participation. CanAge was granted Interested Party status. No interrogatories were completed during the interrogatory process. There was one submission of information by the Interested Party. The committee received six submissions via the alternate method of participation.

At 11:10 a.m. on June 7, 2021, D. Kelly welcomed Ms. Anjli Acharya. Ms. Acharya is a clinical pharmacist specializing in immunization and was contracted by NAPRA to provide an independent review of the literature regarding non-live recombinant herpes zoster vaccine (RZV). She gave a concise slide presentation to the committee, which was followed by a question and answer period.

At 12:50 p.m. on June 7, 2021, D. Kelly welcomed representatives from CanAge: Ms. Laura Tamblyn Watts; Mr. Brett Book, and Mr. Nathaniel Rubin. The CanAge representatives gave a concise presentation to the committee, which was followed by a question and answer period.

At 1:45 p.m. on June 7, 2021, D. Kelly welcomed representatives from Glaxo-Smith-Kline (GSK): Ms. Catherine Keogh, Ms. Emanuela De Franco, and Dr. Heather VanSeggelen. 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 of the information previously provided to them for review and consideration, as well as the information received during each of the presentations and the subsequent question and answer periods.

RZV is indicated for the prevention of herpes zoster in adults 50 years of age or older. The only contraindication is for patients with a known hypersensitivity to any component of the vaccine. As a preventative therapy, a diagnosis is not required to confirm the need for the drug and additional evaluations to prove previous varicella zoster (chicken pox) infection such as checking antibody titres are neither required nor recommended according to Canadian and international guidelines. The committee agreed that a patient could self-identify the need for RZV based on age and interest, but that a regulated health professional such as a pharmacist should confirm the need for the drug and assess the patient for contraindications, previous vaccination status, previous herpes zoster infection, and immunocompromised status in order to ensure appropriate and optimal use of the drug.

Many stakeholders indicated support for a change to Schedule II status via the Interested Party and Alternate Method of Participation processes in order to increase access to this

vaccine and promote vaccine uptake. Stakeholders noted that although shingles is rarely life-threatening, it can create a significant burden of frailty and can have downstream effects on quality of life, hospitalizations and long-term care admissions. This highlights the importance of optimizing the use of shingles vaccines. It was noted that the requirement for a prescription was acting as a barrier to access and was creating inequitable access to this vaccine across the country. Members agreed that a pharmacist could safely complete the required assessments to confirm that RZV is appropriate for each particular patient and that this could remove barriers and promote equitable access to RZV across the country. There was also evidence to suggest that pharmacists could play a role in identifying patients who would benefit from immunization, increasing vaccination rates and promoting series completion, in order to help prevent the potentially significant burden of shingles.

RZV is an intramuscular, 2-dose series injection that must be administered in a health care setting 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 patients with all of the information they need to know about receiving this vaccine. The committee agreed that a pharmacist is required to ensure that the patient will have the drug administered by a health professional and to expand on the labelling information to ensure safe and appropriate use of the vaccine.

The committee noted that RZV leads to temporary, reactogenic-type adverse drug reactions in a significant percentage of the population. Given that the labelling is not designed for the public, it does not provide enough information for patients about the adverse drug reactions associated with RZV. The committee therefore agreed that a pharmacist is required to provide patient education on the incidence and severity of adverse effects. Providing adequate information to patients about what to expect in terms of adverse effects should help to mitigate patient concerns and promote adherence to the second dose.

D. Kelly 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 non-live recombinant herpes zoster vaccine:

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

The committee discussed the overall best fit for the scheduling of non-live recombinant herpes zoster vaccine.

MOTION: It was moved by M. Brown, seconded by J. Kielly to recommend that:

- Non-live recombinant herpes zoster vaccine 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.

It was noted that when the National Drug Schedules are updated, it will be important to clarify via footnote that the live herpes zoster vaccine has not been specifically reviewed by the NDSAC, therefore it would follow the general vaccine listings.

5.0 Updates

5.1 Natural and Non-prescription Health Products Directorate

Dr. M. Ntemgwa shared information regarding Health Canada's proposed precautionary cross labelling of non-steroidal anti-inflammatory drugs (NSAIDs) at 20 weeks or later in pregnancy following the United States Food and Drug Administration safety communication. He shared information on Health Canada's ongoing investigation of nitrosamine impurities in medications by companies marketing human prescription and non-prescription medications. He provided an update on an ad hoc review on non-prescription diphenhydramine single medicinal ingredient - containing products carried out by Health Canada. The committee was informed of Health Canada's decision not to proceed at this time with the regulatory proposal to require a prescription for low dose codeine-containing products. The directorate has been working on the compliance requirements with respect to the Plain Language Labelling (PLL) that came into force on June 13, 2017 with a deadline of June 30, 2021 for non-prescription drugs.

6.0 Next meeting

Tentatively scheduled for September 19-20, 2021.

7.0 Adjournment

The meeting was adjourned at 3:23 p.m. (ET) on June 7, 2021.