

Minutes - National Drug Scheduling Advisory Committee Meeting – June 7, 2026

A virtual meeting of the National Drug Scheduling Advisory Committee (NDSAC) was held on Sunday, June 7, 2026.

Present:

NDSAC members:

Vaughn Chauvin (Chair); Nicolas DesAulniers; Michael Hamilton; Certina Ho; Jaclyn McCarville; Rob Pammett; Marjorie Rempel Friesen

Observers:

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, Sarah ter Huurne, Emily Allan (pharmacy student), Meriam Zeghal (pharmacy student)

Regrets:

Carole Kierstead

Kathy Kovacs Burns – Patients for Patient Safety Canada

1.0 Call to order

1.1 Opening remarks

V. Chauvin welcomed everyone and called the meeting to order at 10:01 a.m. (ET) on Sunday, June 7, 2026. The meeting began with a territorial acknowledgement of the meeting's origins in Ottawa, and of the ancestral and unceded territory from coast to coast to coast of all Inuit, Métis, and First Nations peoples.

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 Rob Pammett as a new member 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 M. Hamilton, seconded by J. McCarville, and approved by consensus.

3.0 Confirmation of approval of the minutes from the December 7, 2025, 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

7, 2025, as posted on the NAPRA website, was put forward by N. DesAulniers, seconded by M. Rempel Friesen, and approved by consensus.

4.0 New Business

4.1 Request for Unscheduled status for bisacodyl 10 mg suppositories in package sizes containing 10 suppositories (100 mg of bisacodyl)

The committee reviewed and considered the application for drug scheduling, as well as additional information submitted through the Alternate Method of Participation. The committee received three submissions via the Alternate Method of Participation. No requests for interested party status were received for this review.

At 10:43 a.m. (ET), V. Chauvin welcomed the representatives from Opella: Giuseppa Gennaro, David Sharp, and Christina Moccia. The Opella 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 the presentation and the subsequent question-and-answer period.

Members were concerned with the potential for misuse and/or abuse of bisacodyl, as indicated in the references, literature, and available post-market data, due to its chemical properties and pharmacological activity as a stimulant laxative. The committee noted that references indicate that individuals with eating disorders seem to make up the majority of those that misuse or abuse stimulant laxatives, but there are other groups that also misuse and abuse stimulant laxatives (e.g., older individuals 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). Since the consequences of such misuse or abuse can be serious, the committee agreed that a pharmacist should be available to provide support and assistance to patients who may be more at risk of misuse and/or abuse 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, clinical trials beyond 4 weeks' duration are lacking. Further, stimulant laxatives are generally not considered first line therapy for the treatment of chronic constipation but rather are recommended to be used on a short-term or rescue basis. The committee agreed that 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 on the current labels. 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. The committee recognized that the outer label does include a warning "for rectal use only" and the foil wrapped suppositories state they are not be swallowed, but the warning was not very prominent and the outer label does not

provide detailed instructions on how to properly insert the suppository. Further, there was no data to show whether patients could understand the warning, and post-market data demonstrated a risk of individuals using the suppository incorrectly (e.g., swallowing the suppository). Additionally, the committee noted that the drug interaction information could be misleading or confusing to some patients. Members also discussed that, since there are many products available for the treatment of constipation, a pharmacist should be available to assist with selecting an appropriate product, including the appropriate route of administration and age range. Members agreed that a pharmacist could also provide advice related to non-pharmacological and lifestyle changes related to constipation and could support patients in understanding the appropriate instructions if using the product prior to medical procedures. The committee therefore agreed that a pharmacist should be available to assist with product selection, promote safe and appropriate use of bisacodyl, and reinforce and expand on product labelling regarding red flags, drug interactions, intended route of administration, and how to use the product correctly.

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 bisacodyl 10 mg suppositories:

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

The committee discussed the overall best fit for the scheduling of bisacodyl 10 mg suppositories. Members discussed the balance between consumer access to the product and maintaining pharmacist oversight of product usage to address concerns with the potential for long-term use, misuse, and abuse. Restricting package sizes that exceed the maximum dose and duration of use approved in the Health Canada Labelling Standard to the pharmacy setting would ensure that a pharmacist is available to monitor for and support patients potentially using the drug inappropriately or on a long-term basis. This would include providing support for patients who may be more at risk of misuse and/or abuse of bisacodyl, supporting patients managing long-term constipation, assisting with product selection, reinforcing or expanding on product labelling, and explaining how to use the product correctly. It was noted that the maximum total treatment dose for the suppositories differs from that for the oral tablets because the approved maximum daily dose in the labelling standard is different for each dosage form.

MOTION: It was moved by M. Hamilton, seconded by M. Rempel Friesen, to recommend that:

Bisacodyl, when sold in strengths of 10 mg or less per rectal dosage unit/suppository, in package sizes containing no more than 70 mg of bisacodyl, be granted Unscheduled Status.

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

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

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Further to the motion, it was confirmed that, since the tablets were not specifically reviewed at this time, bisacodyl, when sold in strengths of 5 mg or less per oral dosage unit, in package sizes containing no more than 105 mg of bisacodyl, would remain Unscheduled.

It was also confirmed that 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 105 mg of bisacodyl and **except** when sold in strengths of 10 mg or less per rectal dosage unit/suppository in package sizes containing no more than 70 mg of bisacodyl, would remain in Schedule III.

5.0 Elections

5.1 Election of Chair

S. ter Huurne called for nominations for the position of Chair of NDSAC. M. Hamilton was nominated and agreed to put forth his candidacy for the position of Chair. No other nominations were received. V. Chauvin moved to appoint M. Hamilton as Chair, seconded by C. Ho, and it was approved by consensus. M. Hamilton was acclaimed as Chair of NDSAC.

5.2 Election of Vice-Chair

S. ter Huurne called for nominations for the position of Vice-Chair of NDSAC. M. Rempel Friesen was nominated and agreed to put forth her candidacy for the position of Vice-Chair. No other nominations were received. M. Hamilton moved to appoint M. Rempel Friesen as Vice-Chair, seconded by N. DesAulniers, and it was approved by consensus. M. Rempel Friesen was acclaimed as Vice-Chair of NDSAC.

6.0 Updates

6.1 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.

6.2 Marketed Health Products Directorate

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

7.0 Next meeting

Tentatively scheduled for September 20-21, 2026.

8.0 Adjournment

The meeting was adjourned at 2:25 p.m. (ET) on June 7, 2026.