Minutes - National Drug Scheduling Advisory Committee Meeting – December 7, 2025

A virtual meeting of the National Drug Scheduling Advisory Committee (NDSAC) was held on Sunday, December 7, 2025.

Present:

NDSAC members:

Vaughn Chauvin (Chair); Nicolas DesAulniers; Michael Hamilton; Certina Ho; Husayn Kassam; Carole Kierstead; Jaclyn McCarville; Marjorie Rempel Friesen

Observers:

Kathy Kovacs Burns – Patients for Patient Safety Canada
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 – Director, Policy and Professional and Regulatory Affairs
Sarah ter Huurne – Senior Pharmacist Specialist, Professional and Regulatory Affairs
Krista Jajko – Government Affairs and Project Lead, Professional and Regulatory Affairs

1.0 Call to order

1.1 Opening remarks

V. Chauvin welcomed everyone and called the meeting to order at 10:03 a.m. (ET) on Sunday, December 7, 2025. 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 Kathy Kovacs Burns as the new observer from Patients for Patient Safety Canada.

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 C. Kierstead, and approved by consensus.

3.0 Confirmation of approval of the minutes from the June 1, 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 June 1,

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

4.0 New Business

4.1 Request for Schedule II status for acetaminophen and ibuprofen, when sold in oral, fixed-dose combinations, in package sizes containing either more than 25,000 mg of acetaminophen or more than 12,500 mg of ibuprofen and

Request for Schedule III status for acetaminophen and ibuprofen, when sold in oral, fixed-dose combinations, in package sizes containing 25,000 mg or less of acetaminophen and 12,500 mg or less of ibuprofen

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 two submissions via the Alternate Method of Participation.

At 10:42 a.m. (ET), V. Chauvin welcomed the representatives from Haleon: Chanbin Kim, Peter Gao, and Stella Chan. The Haleon 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 noted that fixed dose combinations (FDCs) of acetaminophen and ibuprofen were reviewed in June 2020 and December 2023. The committee acknowledged that, since the last review, there was additional post-market experience with FDCs of acetaminophen and ibuprofen, including in Quebec where larger package sizes are available in a Schedule III environment. However, the committee noted that the data was limited and members remained concerned about the potential risks to consumers from FDCs of acetaminophen and ibuprofen, particularly from off-label use in high doses or on a long-term basis. While the safety profile of FDCs of acetaminophen and ibuprofen appears to remain consistent with that of the individual ingredients and no new safety signals were identified, the individual ingredients are known to cause serious adverse events which are documented in the product monographs, post-market surveillance, and in the literature. For example, ibuprofen may increase the risk of cardiovascular events, renal toxicity, and gastrointestinal toxicity including stomach bleeding. Acetaminophen may cause liver toxicity, especially when used off-label in high doses. While there is no evidence of a pharmacokinetic interaction between acetaminophen and ibuprofen, there is evidence that both drugs can cause serious interactions with many other medications. Although serious adverse events and interactions with acetaminophen and ibuprofen are uncommon at the non-prescription dose and duration of use, the committee noted that patients with risk factors are more susceptible to experiencing serious adverse events, even at normal therapeutic dosage levels, and that the risks have been shown to augment with increased dose and duration of use.

The committee discussed concerns with long-term use, given the increased risks of adverse events with increased duration of use. Additionally, although taking a FDC of acetaminophen

and ibuprofen for the non-prescription duration of use of three to five days is not expected to significantly delay recognition or mask the symptoms of serious disease, longer treatment could potentially cause issues in this regard. While FDCs of acetaminophen and ibuprofen are only indicated for short-term use, there is evidence that acetaminophen and ibuprofen are used on a persistent, chronic or recurrent basis. The labels submitted in this review included mention of chronic or recurring conditions such as arthritis, backache, menstrual pain, and migraine pain. Given the risks of serious adverse events, the committee agreed that patients using the drug on a chronic, persistent, or recurring basis should consult with a pharmacist to determine appropriateness, monitor for adverse events, and determine whether further health professional intervention is required.

Members also discussed the risks of high doses leading to acetaminophen-induced liver toxicity. Misuse of acetaminophen resulting in overdose, including inadvertent duplication of treatment linked to confusion in product selection, has been well documented in the literature. There is evidence that indicates that labelling is not sufficient to prevent the risks of unintentional acetaminophen overdose. Given the large number of warnings required for each active ingredient on the labelling of FDCs of acetaminophen and ibuprofen, the committee determined that a pharmacist should be available to provide education on the potential risks of acetaminophen-induced liver toxicity and to reinforce the appropriate dose and duration of use.

Further, the committee noted that a pharmacist should be available to reinforce or expand on product labelling and assist with product selection. As noted earlier, the labelling for FDCs of acetaminophen and ibuprofen can be complex and overwhelming due to the many warnings required for each active ingredient. Many of these warnings on the outer label are therefore very general and non-specific statements, providing patients with minimal information to assist with self-selection. The committee determined that the availability of a pharmacist could help patients interpret the label and determine which warnings may apply to them. Members acknowledged that the labelling was updated since the last review, when the label comprehension study had not met pre-defined success criteria for some of the most important safety considerations. However, since the changes were not tested with a new label comprehension study, there was no evidence that these changes would improve patient understanding or outcomes, especially considering other literature indicating that labelling is not sufficient to prevent the risks of unintentional acetaminophen overdose. There was agreement that a pharmacist could assist patients in determining when the FDC of acetaminophen and ibuprofen might be appropriate for them, amongst the vast number of products available to treat pain and fever, as well as educate on the risks of overdose and long-term use of acetaminophen and ibuprofen outlined above.

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 fixed-dose combinations of acetaminophen and ibuprofen:

- #I-4, I-6, II-2, II-8, III-1, III-3, III-5

The committee discussed the overall best fit for the scheduling of FDCs of acetaminophen and ibuprofen. The committee agreed that a pharmacist must be available to reinforce or expand on complex product labelling and assist with product selection, especially given the potentially confusing and overwhelming amount of warnings and information on the labels of FDCs of

acetaminophen and ibuprofen and the fact that patients with risk factors are more susceptible to experiencing serious adverse events, even at normal therapeutic dosage levels.

Members agreed that the greatest potential risks to consumers of FDCs of acetaminophen and ibuprofen continue to be the risks of acetaminophen overdose and of long-term use, which can both result in serious adverse events, including liver toxicity, cardiovascular events, renal toxicity, and gastrointestinal toxicity including stomach bleeding. Members acknowledged the additional information provided during this review, but determined that it did not include significant evidence to support a change in the scheduling of FDCs of acetaminophen and ibuprofen. Therefore, the committee determined that package sizes above the maximum dose and duration of use for the non-prescription environment of each of the individual active ingredients should remain in Schedule II, to ensure the opportunity to reinforce the appropriate dose and duration of use, and ensure assessment and monitoring, to reduce the risks of high doses and chronic, persistent or recurrent use.

MOTION: It was moved by N. DesAulniers, seconded by H. Kassam, to recommend that:

Acetaminophen and ibuprofen, when sold in oral, fixed-dose combinations, in package sizes containing either more than 20,000 mg of acetaminophen or more than 6,000 mg of ibuprofen remain in Schedule II, and

Acetaminophen and ibuprofen, when sold in oral, fixed-dose combinations, in package sizes containing 20,000 mg or less of acetaminophen and 6,000 mg or less of ibuprofen 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.

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 Products Directorate

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

6.0 Next meeting

Tentatively scheduled for March 22-23, 2026.

7.0 Adjournment

The meeting was adjourned at 2:53 p.m. (ET) on December 7, 2025.