

Minutes - National Drug Scheduling Advisory Committee Meeting – September 20, 2026

A meeting of the National Drug Scheduling Advisory Committee (NDSAC) was held on Sunday, September 20, 2026, at the Lord Elgin Hotel, Ottawa.

Present:

NDSAC members:

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

Observers:

Kathy Kovacs Burns (virtual attendance) – Patients for Patient Safety Canada
Kevin Bernardo (virtual attendance) – Marketed Health Products Directorate, Health Canada
Michel Ntemgwa - Natural and Non-prescription Health Products Directorate, Health Canada

NAPRA Staff – Committee Secretariat:

Sarah Marshall; Sarah ter Huurne; Krista Jajko (virtual attendance)

1.0 Call to order

1.1 Opening remarks

M. Hamilton welcomed everyone and called the meeting to order at 9:02 a.m. (ET) on Sunday, September 20, 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 of all Inuit, Métis, and First Nations peoples.

1.2 Roll call and declaration of quorum

M. Hamilton noted the members in attendance and declared quorum.

1.3 Conflict of interest declarations

M. Hamilton called for conflict-of-interest declarations. None of the members had any conflicts of interest to declare.

1.4 Confidentiality Reminder

M. Hamilton 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 V. Chauvin, seconded by N. DesAulniers, and approved by consensus.

3.0 Confirmation of approval of the minutes from the June 7, 2026, 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 7, 2026, as posted on the NAPRA website, was put forward by M. Rempel Friesen, seconded by J. McCarville, and approved by consensus.

4.0 New Business

4.1 Request for Schedule II status for epinephrine nasal spray, in pre-filled devices intended for emergency administration by nasal spray in the event of anaphylactic reactions to allergens

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

At 9:45 a.m. (ET) on September 20, 2026, M. Hamilton welcomed representatives from ALK: David Grabowski and Matteo Toumeh. The ALK representatives gave a concise presentation to the committee, which was followed by a question-and-answer period.

At 10:45 a.m. (ET) on September 20, 2026, M. Hamilton welcomed representatives from Food Allergy Canada virtually: Jennifer Gerdtz and Ranjit Dhanjal. The Food Allergy Canada representatives gave a concise 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 presentations and the subsequent question-and-answer periods.

Members emphasized that epinephrine is the only available life-saving intervention for the treatment of anaphylaxis and that delays in treatment have been shown to lead to more severe and/or fatal outcomes. Therefore, the drug must be readily available under exceptional circumstances when a prescription is not practical. However, the committee agreed that patients and caregivers purchasing epinephrine require pharmacist education and advice. Members noted that, while patients, caregivers, and bystanders can learn to identify the signs and symptoms of anaphylaxis and a health professional is not required to confirm anaphylaxis before epinephrine is administered in an emergency, one of the documented barriers to prompt use of epinephrine in community settings is failure to recognize anaphylaxis symptoms. Pharmacist engagement is required to provide ongoing education to reinforce the public's ability to recognize the signs and symptoms of anaphylaxis to ensure prompt treatment. A pharmacist should also confirm that the intended use is to treat anaphylaxis prior to selling epinephrine, to help prevent misuse for incorrect indications and the potential of misuse for performance enhancement. Additionally, a pharmacist is required to provide advice about the need for adjunctive evaluation, including when emergency medical attention is required and evaluating the need for a second dose if the first dose is not effective or symptoms return.

The committee discussed the overall safety of nasal epinephrine. Members noted that while no serious adverse effects associated with the use of nasal epinephrine have been reported to date, serious or significant adverse reactions are possible with epinephrine, particularly due to the drug's effects on the cardiac system. Additionally, serious drug interactions have been documented, including in the Product Monograph. The committee agreed that serious drug interactions and

significant adverse reactions are possible and documented, however, given the indicated dose and the drug's duration of action, they are less likely to occur and should not prevent or delay the use of epinephrine in treating anaphylaxis. Therefore, it is important that a pharmacist discuss potential drug interactions and adverse reactions with patients and caregivers, emphasize that these should not delay or prevent treatment with epinephrine, and explain how to manage adverse reactions and drug interactions for each patient's specific situation to ensure the best possible patient outcomes.

The committee observed that epinephrine in this drug delivery system is new to the Canadian market and has limited global experience. The administration instructions for this nasal spray device differ from many other nasal sprays (e.g., no priming, no sniffing, single use, second dose in same nostril). Additionally, it was noted that some of the label information may be confusing or alarming (e.g., instructions for use, drug interaction information) or incomplete (e.g., storage information). The committee noted that if the product is not used correctly, there is a risk of insufficient epinephrine exposure which can have serious consequences, since the product is used to treat life-threatening anaphylaxis. It was agreed that pharmacist intervention is required to reinforce and expand on the product labelling, including ensuring that patients and caregivers are trained on proper use of this new nasal spray to ensure adequate anaphylaxis treatment, clarifying potentially confusing, missing, and alarming label information, emphasizing the importance of prompt epinephrine treatment in all cases, emphasizing the need to monitor and administer a second dose if required, and explaining when to seek emergency care after use. Members also agreed that, with the addition of this new nasal dosage form, product selection may cause confusion, and pharmacists will need to assist patients and caregivers in selecting the most appropriate product for their specific situation and being aware of look-alike, sound-alike products. The committee further noted that anaphylaxis can be recurring, but there may be a long interval before the patient needs to use and/or repurchase the drug and therefore patients and caregivers may not remember all relevant information, especially for this newer delivery device. In fact, many references recommend regular retraining on appropriate use of epinephrine. As such, the committee agreed that a pharmacist must also intervene prior to repurchase, to ensure ongoing retraining, and to confirm whether the product remains the most appropriate for the patient's current circumstances.

M. Hamilton 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 epinephrine nasal spray:

- #I-2, I-6, II-1, II-2, II-3, II-6, II-8, II-9, II-10, III-2, III-3, III-4, and III-5

The committee discussed the overall best fit for the scheduling of epinephrine nasal spray. Members emphasized the importance of reducing any barriers to access to this life-saving treatment that a prescription requirement might present. However, it was agreed that a Schedule III or Unscheduled environment would not be appropriate since patients and caregivers purchasing epinephrine require pharmacist intervention to provide ongoing education about the signs and symptoms of anaphylaxis, assist with product selection, prevent misuse, explain the appropriate management of potential drug interactions and adverse reactions, reinforce correct administration technique, clarify storage requirements, provide retraining and confirm product

selection upon repurchase, and emphasize the need for prompt administration of epinephrine in all cases, the need to monitor and administer a second dose when required, and when to seek emergency care after use. Given the need for prompt access to this life-saving product and the need for initial and continued education to ensure safe and appropriate selection and use, the committee determined that Schedule II was the most appropriate scheduling for epinephrine nasal spray.

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

- Epinephrine nasal spray, when indicated for emergency treatment of anaphylactic reactions, 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 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 December 6-7, 2026.

7.0 Adjournment

The meeting was adjourned at 2:49 p.m. (ET) on September 20, 2026.