A meeting of the National Drug Scheduling Advisory Committee (NDSAC) was held via electronic participation from October 4-10, 2018.

Meeting procedure:

A meeting of the National Drug Scheduling Advisory Committee (NDSAC) was convened by Chair, Tom Bailey, to be held October 4-10, 2018 via electronic participation. The purpose of this meeting was to finalize the NDSAC recommendation regarding the *Request for Schedule III status for esomeprazole magnesium trihydrate 20 mg delayed release capsules when sold for the 14-day treatment for frequent heartburn for the following package sizes: 280 mg (14 capsules), 560 mg (28 capsules), 840 mg (42 capsules)*, which was deferred during the September 9, 2018 meeting pending receipt of the final revised product monograph and labelling for the product.

A notice of the NDSAC meeting was sent via email by the NDSAC secretary, Sarah Marshall, on October 4, 2018, along with the meeting material. The meeting material included the final revised product monograph and labelling documents provided by the applicant, along with a copy of Health Canada's approval of the revised documents.

Members were provided the opportunity to communicate via email after reading the meeting material and then were asked to submit their official vote as to whether or not they continued to support the draft motion made on September 9, 2018.

Attendance:

The following NDSAC members responded to and participated in the email meeting:
Dr. Tom Bailey (Chair); Ms. Kendra Townsend (Vice Chair); Dr. Murray Brown; Dr. Drena Dunford; Dr. Melanie Johnson; Dr. Deborah Kelly; Dr. Jason Kielly, Ms. Joan Sayer

J. McPhee did not participate in the email meeting because she could not attend the September 9, 2018 meeting and therefore was not privy to the original discussions surrounding the draft motion.

The following NAPRA staff participated in the email meeting:
Sarah Marshall, Manager of Professional and Regulatory Affairs, Committee Secretary

NDSAC decision:

After reviewing the final, revised product monograph and labelling received from the applicant, the NDSAC voted to confirm the draft motion made during the September 9, 2018 NDSAC meeting to recommend that:

- esomeprazole or its salts, when sold for the 14-day treatment for frequent heartburn at a daily dose of 20 mg, in package sizes of no more than 280 mg of esomeprazole, be granted Schedule III status, and

- esomeprazole or its salts, EXCEPT when sold for the 14-day treatment for frequent heartburn at a daily dose of 20 mg in package sizes of no more than 280 mg of esomeprazole, be retained in Schedule I;

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

This recommendation will be reported to the NAPRA Board of Directors and published on the NAPRA website, which will trigger the start of the 30-day review period.

Adjournment

The meeting was adjourned at 5:00 p.m (ET) on Wednesday, October 10, 2018.