

A meeting of the National Drug Scheduling Advisory Committee (NDSAC) was held on Sunday, June 11, 2017 at the Lord Elgin Hotel, Ottawa.

Present:

NDSAC members:

Dr. Tom Bailey (Chair), Dr. Murray Brown, Dr. Melanie Johnson, Dr. Deborah Kelly, Dr. Jason Kielly, Ms. Judy McPhee, Ms. Kendra Townsend (Vice Chair)

Observer:

Ms. Joan Sayer – Consumers Association of Canada

NAPRA Staff:

Ms. Adele Fifield – Executive Director

Dr. Sarah Jennings – Acting Manager, Professional and Regulatory Affairs; Committee Secretary

Regrets:

Ms. Drena Dunford

Dr. Ratna Bose – Natural and Non-prescription Health Products Directorate, Health Canada

1.0 Call to order

1.1 Opening remarks

T. Bailey welcomed everyone and called the meeting to order at 9:04 a.m. (ET) on June 11, 2017.

1.2 Conflict of interest declarations

T. Bailey called for conflict of interest declarations. None were declared.

2.0 Approval of the agenda

It was proposed to add a short discussion to clarify the listing of meningococcal vaccines on the National Drug Schedules. A motion to approve the agenda as amended was put forward by K. Townsend, seconded by M. Johnson, and approved by consensus.

3.0 Approval of minutes

3.1 Approval of the minutes from the December 5, 2016 meeting

A motion to approve the minutes from the NDSAC meeting of December 5, 2016 as posted on the NAPRA website was put forward by D. Kelly, seconded by J. McPhee, and approved by consensus.

4.0 New Business

4.1 Request for unscheduled status for minoxidil, when sold in preparations for topical use in concentrations of 5% or less, for human use only.

The committee reviewed and considered the application for drug scheduling. No requests for interested party status and no comments via the alternate method of participation were received for this review.

At 10:15 a.m., T. Bailey welcomed representatives from Johnson & Johnson Inc.: Philloza Suleman, Associate Director, Regulatory Affairs; and Sam Bottner, consultant. The Johnson & Johnson representatives gave a short slide presentation to the committee, which was followed by a question and answer period. The representatives provided samples of their packaged products, which was deemed helpful by committee members.

The committee then discussed the information previously provided to them for review and consideration, as well as the information received during the company presentation and the subsequent question and answer period.

The committee discussed age limits in the Health Canada indications for topical minoxidil products and agreed that it would be prudent to include “for adults” in the listing criteria.

The committee discussed the potential for online sales of topical minoxidil. It was recognized that alopecia may be tied to stigma or self-esteem issues and that many consumers would like to purchase the product online. However, this removes the possibility of consulting with a pharmacist. The committee asked the sponsor for more information regarding their Consumer Care Line.

The committee recognized that some consumers may use topical minoxidil for an inappropriate type of alopecia. The risk of harm associated with this is likely low.

The committee discussed accidental oral ingestion of topical minoxidil. It was noted that the 2% solution is in child-resistant packaging, and that child-resistant packaging is less important for the foam formulations. One committee member consulted with their provincial poison control centre for information about minoxidil and Rogaine® exposures and determined that there had been very few reported exposures over the last five years and none of these cases had led to serious outcomes.

T. Bailey 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 topical minoxidil:

- #III-3

The committee discussed the overall best fit for this drug. It was agreed that some factors applicable in 2014 are no longer applicable. The drug and its formulations are not new to the Canadian market or to self-care. The sponsor presented all adverse events reported in Canada from 2010 to 2016, as well as a Canadian label comprehension study. Although one of the Schedule III factors still applies, the committee agreed that the best fit for these products is Unscheduled status.

MOTION: It was moved by K. Townsend, seconded by M. Johnson, to recommend that: **minoxidil, when sold in preparations for topical use in adults in concentrations of 5% or less, be granted Unscheduled status.**

Motion carried.

This recommendation will be reported to the NAPRA Executive Committee.

5.0 Updates

5.1 Natural and Non-prescription Health Products Directorate

Dr. R. Bose provided an update (by email) on the regulatory requirements with respect to the Plain Language Labelling that will be coming into force on June 13, 2017 for non-prescription drugs. Information on several documents that are now available on the Health Canada's web site was shared.

5.2 NAPRA review of the NDS program

A. Fifield provided an update on NAPRA's review of the NDS program. NAPRA has conducted interviews with its members regarding the value and sustainability of the program and a report on findings has just been presented to members.

5.3 Meningococcal vaccines

Meningococcal vaccines are currently listed as Schedule II drugs because they meet both of the criteria for Schedule II vaccines:

- part of a routine immunization program in most/all provinces and territories
- require special enhanced public access due to outbreaks

NAPRA staff were asked whether meningococcal B vaccine (4CMenB or Bexsero®) is included in this listing.

The committee recognized that meningococcal B vaccine is not part of a routine immunization program in any Canadian jurisdiction and is not recommended for such use by the National Advisory Committee on Immunization (NACI). In an outbreak situation, the need for a serogroup B vaccine would be identifiable only by a practitioner or public health official.

On balance, the committee felt that meningococcal B vaccine is sufficiently different from other meningococcal vaccines that it should be treated as Schedule I. The committee also recommended that the listing criteria for vaccines should have a fulsome review at a future meeting as time allows.

6.0 Next meeting

Tentatively set for September 10-11, 2017.

7.0 Adjournment

The meeting was adjourned at 12:09 p.m.