A meeting of the National Drug Scheduling Advisory Committee (NDSAC) was held via teleconference on Thursday, July 3, 2014 at 3 p.m. (ET).

Present:

NDSAC members:

Dr. Carlo Marra (Chair); Dr. Tom Bailey; Drena Dunford; Dr. Deborah Kelly, Kathy McInnes; Judy McPhee

Observers:

Joan Sayer – Consumers Association of Canada

NAPRA Staff:

Carole Bouchard – Executive Director
Sarah Marshall – Manager, Professional and Regulatory Affairs, Committee Secretary

Regrets:

Dr. Murray Brown; Kendra Townsend; Dr. Ratna Bose

1.0 Call to order

1.1 Opening remarks

C. Marra welcomed everyone and called the meeting to order at 3:02 p.m. (ET) on July 3, 2014.

1.2 Conflict of interest declarations

C. Marra called for conflict of interest declarations. None of the members had any conflicts of interest to declare.

2.0 Approval of the agenda

A motion to approve the agenda as presented was put forward by K. McInnes, seconded by D. Kelly and approved by consensus.

3.0 Approval of minutes

3.1 Approval of the minutes from the June 8-9, 2014 meeting

A motion to approve the minutes from the NDSAC meeting of June 8-9, 2014 was put forward by T. Bailey, seconded by J. McPhee and approved by consensus.

4.0 Follow-up matters

4.1 Follow-up re: request for Schedule III status for minoxidil foam 5% for topical use for female androgenetic alopecia.

The committee discussed the additional information and clarification and revised Product Monograph received from the sponsor, along with the indication that Health Canada approved the revision. Members noted that some of the information requested in regards to the consumer usage study was not available. After further discussion, however, it was determined that the absence of this information would not prevent the committee from formulating its recommendation. The committee proceeded to review the applicability of the scheduling factors as discussed at the June meeting in light of the information, clarification and revised Product Monograph received from the sponsor.

Members reaffirmed the fact that female pattern hair loss is a condition that is new to self-selection in Canada and thus the ingredient is new for women to self-select. The committee continued to be of the opinion that a pharmacist should be available to help with self-selection and expand on product labelling and instructions for use. It was noted that the instructions for use were quite lengthy and were more complex than the directions for use in men. Members were concerned that some patients may have difficulty understanding or remembering all of the cautions and steps required for proper application, particularly due to concerns with the population tested in the label comprehension study. Information regarding who should use the product was some of the least well understood information in the Canadian label comprehension study. In addition, the age range of women in the label comprehension study did not match the age range of women in the clinical trials and thus may not have been representative of the target population.

Members agreed that a pharmacist should be available to help patients identify contraindications such as hypertension, patchy hair loss or the use of interacting medications and help them determine when to stop the medication, for example if there is no improvement in 6 months or if they have started a topical corticosteroid or developed hypertension or cardiovascular disease. Members also discussed the importance of having a pharmacist available to help manage expectations regarding this drug by elaborating on the likely magnitude and duration of its effect and helping women weigh the level of benefit and risks of this drug versus other available treatment options.

The committee agreed that the following scheduling factors were applicable to minoxidil foam 5% for topical use for female androgenetic alopecia.

- #II-10, III-2, III-3 and III-5

The committee agreed that considering the weight of each applicable factor, the schedule that best fit this drug was Schedule III.

MOTION: It was moved by D. Kelly, seconded by T. Bailey to recommend that **minoxidil foam for topical use in concentrations of 5% or less for female androgenetic alopecia (female pattern hair loss) be granted Schedule III status, subject to removal from the Prescription Drug List.**

Motion carried. All members agreed to the above noted motion.
This recommendation will be reported to the NAPRA Executive Committee.

5.0 Next meeting

The next meeting is tentatively scheduled for September 7-8, 2014

6.0 Adjournment

A motion to adjourn was put forward by K. McInnes, seconded by D. Kelly and approved by consensus. The meeting was adjourned at 3:15 p.m. (ET).