

A meeting of the National Drug Scheduling Advisory Committee (NDSAC) was held via teleconference on Thursday, May 15, 2014 at 1 p.m. (ET).

Present:

NDSAC members:

Kathy McInnes (Chair); Dr. Tom Bailey; Dr. Murray Brown; Drena Dunford; Dr. Deborah Kelly, Judy McPhee, Kendra Townsend

Observers:

Joan Sayer – Consumers Association of Canada

NAPRA Staff:

Carole Bouchard – Executive Director

Sarah Marshall – Manager, Professional and Regulatory Affairs, Committee Secretary

Regrets:

Dr. Carlo Marra (Vice Chair)

Dr. Ratna Bose – Natural Health Products Directorate, Health Canada

1.0 Call to order

1.1 Opening remarks

K. McInnes welcomed everyone and called the meeting to order at 1:03 p.m. (ET) on May 15, 2014.

1.2 Conflict of interest declarations

K. McInnes 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. Townsend, seconded by T. Bailey and approved by consensus.

3.0 Follow-up matters

3.1 Follow-up re: request for Unscheduled status for diclofenac and its salts, when sold as a single medicinal ingredient for topical use on the skin in a concentration equivalent to 2% or less diclofenac for not more than 7 days.

The committee discussed the additional information and clarification received from the sponsor in response to the March 9-10, 2014 NDSAC meeting. Members agreed that all of the requested information and clarification was received.

The committee proceeded to review the applicability of the scheduling factors as discussed at the March meeting in light of the information and clarifications received from the sponsor. The committee again discussed their concerns related to the potential for the drug to be used off-label for chronic conditions and the risks associated with chronic use. The committee noted that the drug is recommended for the treatment of

chronic conditions in the literature and is approved and promoted for the treatment of chronic conditions in other countries. Members concurred that a pharmacist should be available to reinforce the risks of long-term use and to promote appropriate use. Members agreed that the maximum quantity of diclofenac diethylamine in a package should be proportionate to the amount required for a few possible usages per year of the approved daily dosage and duration of use.

The committee acknowledged the clarifications in the product information received from the sponsor to make it easier for patients to understand potential drug interactions and warnings not to use the drug under an occlusive dressing. In light of these clarifications, the committee re-considered the applicability of factor #II-8 previously discussed and determined that it was not applicable.

The committee is of the opinion that product selection would be enhanced by accessibility to a pharmacist. Members cited a number of different reasons that could potentially cause confusion in product selection. These included, for instance, the availability of a number of topical diclofenac line extensions, lack of clarity in line extension product names and product marketing and the potential for confusion between different age ranges and directions for use of line extensions. The committee noted the lack of available consumer usage studies to demonstrate the consumer's ability to appropriately differentiate between available products and correctly self-select and use this drug. The committee agreed that a pharmacist should be available to assist the patient with product selection and promote appropriate use.

It was agreed that the following scheduling factors were applicable to topical diclofenac diethylamine 2.32%:

- #II-2, #III-3, #III-5.

MOTION: It was moved by D. Dunford, seconded by J. McPhee: **to recommend that:**

diclofenac diethylamine, when sold as a single medicinal ingredient for topical use on the skin for not more than 7 days in concentrations greater than 1.16% and less than or equal to 2.32% in package sizes containing no more than 2.6g of diclofenac diethylamine be granted Schedule III status

and that diclofenac diethylamine, when sold as a single medicinal ingredient for topical use on the skin for not more than 7 days in concentrations greater than 1.16% and less than or equal to 2.32% in package sizes containing greater than 2.6g of diclofenac diethylamine be granted Schedule II status

and that diclofenac diethylamine, when sold as a single medicinal ingredient for topical use on the skin in concentrations of 1.16% for not more than 7 days remain Unscheduled.

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

This recommendation will be reported to the NAPRA Executive Committee.

3.2 Follow-up re: request for Schedule III status for minoxidil foam 5% for topical use.

The committee reviewed and discussed the revised product information received from the sponsor along with the indication that Health Canada had approved the revisions. Members were in agreement that the inconsistencies previously noted in the product information were adequately corrected and addressed in the revised product information. Members concurred that the draft motion of March 9-10, 2014 could now be finalized by the committee.

MOTION: It was moved by K. Townsend, seconded by T. Bailey: **to recommend that minoxidil foam for topical use in concentrations of 5% or less for male androgenetic alopecia (male pattern baldness) be granted Schedule III status.**

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

This recommendation will be reported to the NAPRA Executive Committee.

4.0 Next meeting

June 8-9, 2014 in Ottawa

5.0 Adjournment

A motion to adjourn was put forward by T. Bailey and approved by consensus. The meeting was adjourned at 1:40 p.m. (ET).