

A meeting of the National Drug Scheduling Advisory Committee (NDSAC) was held on Sunday, March 9 and Monday, March 10, 2014 at the Lord Elgin Hotel, Ottawa.

**Present:**

**NDSAC members:**

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

**Observers:**

Dr. Ratna Bose – Natural Health Products Directorate, Health Canada (Sunday only)  
Joan Sayer – Consumers Association of Canada

**NAPRA Staff:**

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

**1.0    Call to order**

**1.1    Opening remarks**

K. McInnes welcomed everyone and called the meeting to order at 9:32 a.m. on March 9, 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 D. Dunford and approved by consensus.

**3.0    Approval of the minutes from the December 8, 2013 meeting**

A motion to approve the minutes from the NDSAC meeting of December 8, 2013 as posted on the NAPRA website was put forward by C. Marra, seconded by M. Brown and approved by consensus.

**4.0    New Business**

**4.1    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 reviewed and considered the application for drug scheduling. No requests for interested party status were received for this review. No submissions were received via the alternate method of participation.

At 10:30am on Sunday, March 9, 2014, K. McInnes welcomed Mr. Don Beatty, Director of Scientific and Regulatory Affairs, Novartis Consumer Products Inc. Mr. Beatty gave a short slide presentation to the committee regarding the 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, which was followed by a question and answer period.

During the question and answer period, certain discrepancies in the product monograph and product labelling were noted. The sponsor indicated that some information that should be included in the labelling appeared to be missing from the product labelling that was provided to the NDSAC members. The sponsor agreed to look into the matter and provide clarification to the committee as soon as possible.

The committee then discussed the information previously provided to them for review and consideration, as well as the information received during the company's presentation and the subsequent question and answer period. Members discussed concerns related to the potential for product selection to cause confusion and the lack of available consumer usage studies to address this; the potential for the drug to be used off-label for chronic conditions and the risks associated with chronic use; as well as the potential need for a pharmacist to expand on missing or limited information on the product labelling such as drug interactions. Members agreed that they could not come to a definite conclusion on any of these points until they received additional information from the sponsor to clarify potential discrepancies.

Accordingly, members felt that they could not proceed to a recommendation at this point in time. The committee agreed to request additional information and clarification from the sponsor prior to formulating its interim recommendation.

**MOTION: It was moved by J. McPhee, seconded by D. Dunford: that the recommendation for scheduling be deferred until the information and clarification requested on this product is obtained and considered by the committee.**

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

The 30-day consultation period will not begin until the information and clarification requested on this product is obtained and considered by the committee and a recommendation for scheduling is finalized and forwarded to the NAPRA Executive Committee.

#### **4.2 Request for Schedule III status for minoxidil foam 5% for topical use.**

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

At 10:00am on Monday, March 10, 2014, K. McInnes welcomed Mr. Sam Bottner, Senior Manager Regulatory Affairs; Ms. Felicia Mohammed, Manager Regulatory Affairs and Ms. Philloza Suleman, Sr. Manager Regulatory Affairs from Johnson and Johnson Inc. Mr. Bottner gave a short slide presentation to the committee regarding the request for Schedule III status for minoxidil foam 5% for topical use, which was followed by a question and answer period.

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

There was some concern about the significance of potential drug interactions with topical minoxidil, but members agreed that the product labelling was sufficient to address these. There was some concern that less safety data was available for the 5% foam formulation, since it was a newer product. However, members also noted that the 5% foam formulation appeared to have a more favorable pharmacokinetic and safety profile than the 2% solution.

The committee agreed that a pharmacist should be available to reinforce when the drug should not be used and when it should be stopped. A pharmacist can help patients confirm whether they should start taking this drug, for example by helping them identify whether they have hypertension. As well, since the drug is used chronically, a pharmacist can help patients identify when they should stop the medication, for example if they have reached age 65, started a topical corticosteroid or developed cardiovascular disease. Patients using the drug for many years could also benefit from having the pharmacist periodically remind them of important safety points, as they may not re-read the product information with every purchase.

Members agreed that the pharmacist has an important role to play in helping patients manage their expectations with regards to the drug. The pharmacist can elaborate on how long it will take to see an effect, how large of an effect the patient is likely to experience and how long the effect is likely to last. A pharmacist should be available to help the patient weigh the level of benefit and risks of this medication versus other available treatment options to help with product selection. The pharmacist can also help the patient decide how long to continue treatment based on adverse effects, the level of benefit they are experiencing and whether they are experiencing declining effects.

The committee was also of the opinion that a pharmacist should be available to reinforce or expand on product labelling. It was noted that the instructions for use were quite long and complex. Members were concerned that some patients may have difficulty understanding or remembering all of the cautions and steps required for proper application. Members agreed that the user testing of the patient leaflet study provided did not alleviate these concerns, since it was carried out on labelling in the UK which differed significantly from the Canadian labelling and in a population that was not representative of the population in whom the drug is indicated.

In addition, the committee noted two inconsistencies in the Product Monograph and Consumer Information Leaflet, which were not corrected in time for the meeting. The sponsor acknowledged these inconsistencies and assured members that the appropriate corrections to the Product Monograph and Consumer Information Leaflet would be made shortly.

K. McInnes led the group in a review of the applicability of the National Drug Scheduling Factors. It was agreed that, assuming the appropriate corrections were made to the product information, the following scheduling factors were applicable to minoxidil foam 5% for topical use for male androgenetic alopecia.

- #II-10, #III-3, #III-5.

The committee did not want to finalize its recommendation until it had a chance to review the corrections to the inconsistencies in the product information. However, it

agreed that a draft motion could be made pending receipt and review of the corrected Product Monograph and Consumer Information Leaflet.

A draft motion was put forward:

It was moved by T. Bailey, seconded by M. Brown: **that minoxidil foam for topical use in concentrations of 5% or less for male androgenetic alopecia (male pattern baldness) be granted Schedule III status, subject to the correction of inconsistencies in the product information by the sponsor.**

**Draft Motion carried.** All members agreed to the above noted draft motion.

The 30-day consultation period will not begin until the committee has confirmed that the sponsor has corrected the inconsistencies in the product information and has finalized its draft recommendation and forwarded it to the NAPRA Executive Committee.

## **5.0 Updates**

### **5.1 Natural Health Products Directorate (including Non-prescription Drugs Evaluation Division)**

Dr. R. Bose updated on the current work to align requirements and practices for products that carry a similar level of risk in the marketplace.

Dr. R. Bose also shared information on the guidance document for switching medicinal ingredients from prescription to non-prescription status.

Future projects with the US-FDA under the Regulatory Cooperation Council (RCC) and with the Therapeutic Goods Administration's (TGA), Australia as part of the Regulatory Cooperation Initiative (RCI) initiative was also shared.

### **5.2 NDS harmonization with Prescription Drug List**

S. Marshall explained NAPRA's intent to harmonize the National Drug Schedules with Health Canada's Prescription Drug List (PDL) now that Schedule F has been repealed. Historically, not every drug that was listed in Schedule F was listed in the NDS. As well, some of the listings on Schedule F were re-worded slightly when Health Canada published the PDL. NAPRA intends to carry out an exercise to harmonize the NDS with the wording in the PDL. Until this exercise can be completed, a caveat has been added to NDS database on the NAPRA website, indicating that all references in the NDS to Schedule F should now be considered references to the PDL.

### **5.3 NAPRA strategic plan and activities**

C. Bouchard gave a short presentation on NAPRA's strategic plan and activities. She reviewed NAPRA's activities over the past few years and provided information about the current priorities for the NAPRA Board of Directors.

## **6.0 Next meeting**

Tentatively set for June 8-9, 2014.

## **7.0 Adjournment**

The meeting was adjourned at 12:00 p.m. on Monday, March 10, 2014. (ET).