

A meeting of the National Drug Scheduling Advisory Committee (NDSAC) was held on Sunday, September 7, 2014 at the Lord Elgin Hotel, Ottawa.

Present:

NDSAC members:

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

Observers:

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

C. Marra welcomed everyone and called the meeting to order at 9:29 a.m. (ET) on September 7, 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 D. Kelly, seconded by K. Townsend and approved by consensus.

3.0 Approval of the minutes from the July 3, 2014 teleconference

A motion to approve the minutes from the NDSAC teleconference of July 3, 2014 as posted on the NAPRA website was put forward by J. McPhee, seconded by D. Dunford and approved by consensus.

4.0 New Business

4.1 Request for Schedule III status for single medicinal ingredient topical preparations containing 1% or less of hydrocortisone or hydrocortisone acetate.

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 10:30 a.m., C. Marra welcomed representatives from Johnson & Johnson Inc.: Ms. Felicia Mohammed, Regulatory Affairs Manager and Ms. Philloza Suleman, Sr. Manager Regulatory Affairs. Ms. Mohammed gave a short slide presentation to the committee regarding the request for Schedule III status for single medicinal ingredient topical preparations containing 1% or less of hydrocortisone or hydrocortisone acetate, 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.

The committee discussed the proposed name for the product reviewed in this submission. Members expressed concern that the name could be misleading and easily misinterpreted by the public. The name could give consumers the impression that the product is a treatment or cure for a chronic condition, when it is only indicated to relieve the symptoms associated with that condition and can be used for the symptoms of other conditions as well. The name also seems to imply that the product is appropriate for emergency treatment of severe flare-ups, when more potent steroids or other treatments may actually be more appropriate in such cases. The committee asked the sponsor whether there were any consumer studies to support the product name. The sponsor offered to verify and report back to the committee on this matter.

Members also discussed the information available to consumers about this product. It was agreed that a pharmacist should be available to explain potentially confusing scientific terms and symbols in the product labelling such as stasis dermatitis, venous insufficiency and immunosuppressants. In addition, members noted that the labelling does not provide consumers with any information on adverse effects and there is no patient information leaflet that provides this information. Members discussed the adverse effect profile of this drug based on clinical trial and pharmacovigilance data and noted that the risks were minimal when used in appropriate quantities at the approved dosage for no more than 7 days. In light of the favorable adverse effect profile in this situation, the committee concluded that a pharmacist was not required to provide information on every purchase, but should be available to provide this information when needed. Members agreed that a pharmacist should be available to assist patients with product selection by reinforcing appropriate indications for use and contraindications, helping patients choose the correct strength and dosage form and steering patients away from less effective options. The committee was also of the opinion that the availability of a pharmacist to provide education on appropriate application and usage and advice on non-pharmacological adjuncts to treatment would contribute to safe and appropriate use of the drug.

C. Marra 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 hydrocortisone or hydrocortisone acetate in concentrations of 1% or less.

- #III-3 and III-5

Members did have some concerns about the potential for delayed recognition or masking of serious disease, overuse due to rebound flare-ups or other factors and the need for pharmacist monitoring of chronic use, but concluded that the corresponding factors were not applicable for small quantities appropriate to the approved dosage and duration of use. It was noted that a package size of 30 grams as proposed by the sponsor would be consistent with package size restrictions in other jurisdictions. The committee agreed that the best fit for this drug, when sold in package sizes of no more than 30 grams is Schedule III, but that larger package sizes should be placed in Schedule I to allow chronic use of large quantities on large areas of the body to be monitored by a prescriber.

While discussing the best fit for this substance, the committee contemplated whether their recommendation should be restricted to single ingredient hydrocortisone or hydrocortisone acetate or whether they should recommend broader scheduling in anticipation of potential non-prescription combination products containing hydrocortisone or hydrocortisone acetate. The committee decided that by including specifications regarding package size and age range in their recommendations, it was not necessary to restrict the recommendations to single ingredient products.

The committee did not want to finalize its recommendations until it had a chance to review additional information from the sponsor. However, it agreed that a draft motion could be made pending receipt and review of the requested information.

A draft motion was put forward:

It was moved by K. Townsend, seconded by M. Brown: **to recommend that hydrocortisone or hydrocortisone acetate, when sold in a concentration that provides 1% or less hydrocortisone in preparations for topical use on the skin in adults and children 2 years of age and over in package sizes containing no more than 30g, be granted Schedule III status, subject to review of the requested information and removal from the Prescription Drug List ;**

that hydrocortisone or hydrocortisone acetate, when sold in a concentration that provides 1% or less hydrocortisone in preparations for topical use on the skin in adults and children 2 years of age and over in package sizes containing more than 30g, be granted Schedule I status, subject to review of the requested information ;

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

The committee agreed that hydrocortisone or hydrocortisone acetate, when sold in a concentration that provides 1% or less hydrocortisone in preparations for topical use on the skin in children under 2 years of age would be listed in Schedule I.

The 30-day consultation period will not begin until the committee has reviewed the requested information, finalized its draft recommendation and forwarded it to the NAPRA Executive Committee.

5.0 Updates

5.1 Natural and Non-prescription Health Products Directorate

Dr. R. Bose indicated that the name of the Directorate is now changed to Natural and Non-prescription Health Products Directorate. She also provided an update on the acetaminophen Branch-Working Group activities.

Dr. R. Bose also shared information on the upcoming regulatory changes: Consumer Health Products Framework details of the proposed regulations for non-prescription drugs, and consultation with interested stakeholders which will take place this fall.

Bill C-17 (*Vanessa's Law*), if passed into law, will amend the *Food and Drugs Act* regarding therapeutic products. These measures will include new authorities for the Minister, such as an ability to recall unsafe therapeutic products, impose tougher fines and penalties, and direct a label change or package modification. Vanessa's Law will

apply to prescription and over-the-counter drugs, vaccines, gene therapies, cells, tissues and organs, and medical devices. It will not apply to natural health products, which will continue to be regulated under the existing *Natural Health Product Regulations* of the *Food and Drugs Act*.

6.0 Next meeting

Next meeting tentatively set for December 7-8, 2014.

7.0 Adjournment

The meeting was adjourned at 1:51 p.m. (ET) on a motion by T. Bailey, seconded by D. Dunford and agreed to by all members.