A meeting of the National Drug Scheduling Advisory Committee (NDSAC) was held on Monday, June 7, 2010 at the Sheraton Hotel, Ottawa.

Participants

Committee members
Margot Priddle, Chair; Dr. Ruth Wilson, Vice Chair; Kim Abbass; Gail Bradley; Dr. Nancy MacDonald; Dr. Sheldon Koven; Dr. Peter Zed; Kathy McInnes

Observers
Dr. Ratna Bose – Therapeutic Products Directorate, Health Canada
Joan Sayer – Consumers Association of Canada

Staff
Lizanne Beique – NDSAC resource and pharmacist, Ottawa Valley Regional Drug Information Centre
Kathy Vesterfelt –Manager, Professional and Regulatory Affairs, NAPRA, Committee Secretary

1.0 Call to order

1.1 Call to Order

Margot Priddle called the session to order at 8:50 am and welcomed everyone to the meeting. Ms. Priddle informed the members that Carole Bouchard, Executive Director; NAPRA would not be able to attend.

1.2 Conflict of interest declarations

Ms. Priddle called for conflict of interest declarations. None were declared. All participants had previously submitted signed conflict of interest declarations that were still valid.

2.0 Approval of the agenda

The agenda was approved as circulated.

3.0 Approval of the minutes of the March 7-8, 2010 meeting

The minutes had been approved prior to being posted on the NAPRA website

4.0 New Business

4.1 Request for Unscheduled status for polyethylene glycol 3350 indicated for occasional constipation

The Committee welcomed Marie Claude Gagnon, and Dr. Alankar Gupta, representatives from Schering-Plough Consumer HealthCare to the meeting at 9:30 a.m. The representatives made a presentation to the Committee, outlining the Schering-Plough Consumer Healthcare request that the scheduling of polyethylene glycol 3350 indicated for occasional constipation

be changed from Schedule III to Unscheduled status. The presentation was followed by a questions and answers session with committee members. Committee members requested the Applicant provide further data around the Periodic Safety Update Reports (PSUR), consumer usage information, any further information they could provide regarding questions they had received by consumers regarding this product and the American Guidelines Dr. Gupta had referred to in the presentation.

The Committee reviewed and discussed the information previously submitted by the Applicant and their presentation. The Committee members discussed issues related to the safety and efficacy of the product, the potential for off-label used of the product and whether the labelling provided enough information for the consumer to make appropriate self-selection of the product.

The Chair then led the Committee through a review of the current applicability factors of this drug to all scheduling factors, and it was agreed that scheduling factor # III-3 and # III-5 were applicable.

There was agreement that a draft motion could be made pending the outcome of reviewing the requested additional information once received by the sponsor.

A draft motion was put forward:

Polyethylene glycol (PEG) 3350 single ingredient oral products indicated as a laxative to treat occasional constipation would be unscheduled subject to the requested information received from sponsor and reviewed by the NDSAC members.

A. Interested Party Status requests - Ms. Priddle informed the members that there was one written request for Interested Party Status which was denied.
B. Comments received from alternate method of consultation -The Committee members were informed that written comments were received from one company expressing their support for the Applicant's scheduling request.

5.0 Updates

5.1 **Natural Health Products update** - Ms. Vesterfelt provided the Committee with a verbal update of a proposed Natural Health Product Regulation regarding Unprocessed Licence Applications published in Canada Gazette Part I, May 8th, 2010 with a 30 day comment period. This regulatory proposal would provide a temporary instrument to permit natural health products (NHP) for which a product licence application has been filed with Health Canada but a decision to issue or refuse a licence has not been made, to be sold on the market, with an exemption to the prohibition on sale in the *Natural Health Products Regulations* (NHPR). NAPRA provided a written response to the proposed regulation.

5.2 Products listed as "ethical" by Health Canada - Ms. Vesterfelt provided the Committee with an update on the ongoing work NAPRA has been doing following the motion put forward at the December 2009 NDSAC meeting; "to examine the feasibility of developing a policy whereby all drugs identified as "ethical" by Health Canada, would automatically be listed under Schedule II of the NDS". The Committee learned there were over 1000 products listed by Health Canada as ethical, and there have been some roadblocks identified to doing any meaningful analysis. In addition to the large number of products, there is a wide range of products; each product may have multiple medicinal ingredients, and products with a broad range of dosage forms and routes of administration that would not routinely be sold from a community pharmacy. Health Canada has also conducted a review of "ethical" products to evaluate whether they are appropriately listed as such and there may be some changes to the status of some products as a result of their review. NAPRA is communicating closely with Health Canada on this issue.

An update of the work that has been done to date will be shared with the Executive Committee for further review and discussion.

6.0 Other administrative issues

It was brought forward by Committee members, that significant work had been done on guidelines for submissions over the last 5 years but this project had not moved forward in some time. The members expressed some concern that this work had not progressed. Ms. Vesterfelt indicated she would review the file and background information and provide feedback on this issue at the next meeting. Similarly, work on developing a reference chart of scheduling structure in other jurisdictions has not been completed.

It was suggested that asking the Applicant to bring in product samples during the presentation would be helpful for Committee members to have a more visual image of how information is presented on the product container.

R. Wilson suggested that the NDSAC meeting agenda be posted on the secure website for NDSAC members using hyperlinks to accompanying documents. Ms. Vesterfelt informed the members she would look at the feasibility of doing this.

There was discussion of preference to which day the Committee members preferred to meet if the meeting would take place on one day only. The preference indicated by the group was to hold a one day meeting on Sunday. Ms. Vesterfelt indicated that whenever possible that would be how such meetings would be scheduled.

7.0 For Information

7.1 TPD update

Dr. Bose informed the Committee members that Health Canada is continuing discussions with the FDA in US regarding acetaminophen safety issues. After US FDA makes a decision, Health Canada may consider whether regulatory amendments would be required.
An update was provided regarding nanotechnology and Dr. Bose provided information regarding the DIN to NHP transition that is continuing.

8.0 Date of next meeting

Tentatively set for Sept 12-13, 2010

9.0 Adjournment

The meeting was adjourned at 1:40 p.m.