A meeting of the National Drug Scheduling Advisory Committee (NDSAC) was held on Sunday, September 12, 2010 at the Sheraton Hotel, Ottawa.

Participants

Committee members
Dr. Ruth Wilson, Chair; Kathy McInnes, Vice- Chair*; Kim Abbass; Gail Bradley; Dr. Sheldon Koven; Dr. Nancy MacDonald; Margot Priddle; Dr. Peter Zed
* elected under New business item 4.2

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
Carole Bouchard – NAPRA Executive Director
Kathy Vesterfelt – NAPRA Committee Secretary

1.0 Call to order

1.1 Call to Order

Chair R. Wilson called the session to order at 9:00 am and welcomed everyone to the meeting.

1.2 Conflict of interest declarations

R. Wilson called for conflict of interest declarations. Dr. MacDonald indicated she had worked for a company that could be considered a competitor to the company presenting its submission. However, her employment with the company ended with her retirement more than six years ago. The committee members did not feel this represented a conflict of interest. No other members had anything to declare. All participants submitted signed conflict of interest declarations.

2.0 Approval of the agenda

The agenda was approved.

3.0 Approval of the minutes of the June 7th meeting and June 17th teleconference meeting

The minutes of June 7th meeting and June 17th teleconference meeting were approved with no further changes to the documents circulated electronically to Committee members and posted on NAPRA website.

4.0 New business

4.1 Update on Membership

K. Vesterfelt informed the Committee that members, K. Abbass, K. McInnes and P. Zed had completed their first term on the Committee in August 2010 and all expressed interest in continuing their work on the NDSAC. The NAPRA Executive Committee re-appointed all of them for a second three year term to the NDSAC.

A recruitment drive was initiated in late April 2010 to replace outgoing NDSAC member, M. Priddle, whose term on the Committee was coming to an end. A wide range of stakeholders were invited to submit nominations for an individual with expertise in drug utilization. Following a review of the candidates, the NAPRA executive Committee appointed Dr. Carlo Marra to the NDSAC. Dr. Marra's term on the NDSAC will begin October 1st, 2010.

R. Wilson asked the members to review their Committee members' brief biographies that are posted on the NAPRA website and send any updated information to the attention of NAPRA which will be reflected on the website.

4.2 Election of NDSAC Vice-Chair

Chair R. Wilson facilitated the process and asked for nominations from members for the Vice-Chair. It was strongly suggested that members in their first term consider running for the Vice-Chair position. K. McInnes, who was nominated for the position and elected by consensus by the members, accepted the position of NDSAC Vice-Chair.

C. Bouchard will report to the Executive Committee the results of the election.

4.3 NDSAC meeting schedule for 2011

The following dates which had been previously circulated to the members, were tentatively selected for NDSAC meetings in 2011:

March 6-7, 2011
June 12-13, 2011
September 11-12, 2011
December 4-5, 2011.

4.4 NAPRA activities

C. Bouchard made a presentation to the Committee which provided an overview of NAPRA, its organizational structure, vision and mandate, services and initiatives and relationships with pharmacies and pharmacists. The presentation outlined the numerous ongoing activities at NAPRA, accomplishments particularly over the last few years and shared with the members, key priorities for the organization for 2010. Of particular interest for the Committee was the priority identified to initiate the National Drug Schedules Review. While some of the work will commence in the late fall of 2010, the review will continue over the course of the next few years.

4.5 Request for a change in scheduling status of naproxen sodium 220 mg per tablet to Unscheduled.

The Committee was informed that no Interested Parties status was granted for this meeting. Comments were received in writing from six Individuals, companies or organizations through the alternate method of participation. There were four letters supporting the requested scheduling change and two letters that did not indicate support for the requested scheduling change. This information, including additional information provided with the letters was made available to the Committee members.

At 11.00 a.m. K. Vesterfelt introduced representatives from Bayer Consumer Care; Leonard Baum, Vice-President, Regulatory Affairs- North America, Dr. Shirley Chen, Director, Global Medical Affairs, and Joseph Chan, Regulatory Affairs Manager-Canada. The Committee members then introduced themselves.

Mr. Baum made a presentation to the Committee regarding the request for unscheduled status for naproxen sodium 220 mg per tablet for all package (count) sizes. The presentation was followed by a period of questions and answers with Committee members.
The Committee reviewed and discussed the submission previously provided by the applicant and their presentation.

In the NDSAC deliberations following the formal presentation and discussion, it was noted by the Committee members that information on the experience of this product as an OTC in the Canadian market is still very limited. There was concern expressed by Committee members that consumers may be confused over how to use this product appropriately and some consumers may be using the product in larger than recommended doses for unapproved indications. The Committee noted that the applicant's submission did not include consumer usage studies. In the absence of this information in the submission, it was difficult for Committee members to make an assessment of the level of consumer understanding of the proper use of this product. The Committee members asked if the sponsor had conducted consumer usage studies for this product in Canada and were told they had not done any for this product.

It was also noted by Committee members that the data supplied by the sponsor suggested that there might be lower incidence of reported adverse events in Canada than reported globally. While the company offered that this might be related to higher approved dosages elsewhere, this could not be necessarily concluded from the data presented. A Committee member made the suggestion that the lower incidence in Canada might be reflective of the restriction of the sale of this product to a pharmacy with the availability of pharmacist for consultation. Both of the opinions expressed were speculative.

It was noted that there were concerns around the labeling of this product. Members expressed their concerns that the language used in the package insert to describe drug interactions and contraindications is too complex for the average consumer to understand and may make it difficult to make an informed decision for self selection of this product. Further, this important information was not found on the outer container or box and could not be accessed until after the product had been

purchased. There was considerable discussion around the large package sizes available for this product.

The Chair then led the Committee through a review of the current applicability of this drug product to all scheduling factors. The approach taken was to apply the scheduling factors to the product based on the current NDS scheduling status. It was agreed that scheduling factors#1-4, #1-6,#II-2, #II-9, #II-10 #III-2, #III-3 and #III-5 were applicable for package sizes greater than 6,600 mg; scheduling factors #1-4, #1-6 and #II-10 applied to packages sizes less than 6,600 mg.

It was moved by P. Zed, seconded by M. Priddle that Naproxen sodium 220 mg per tablet (when sold in products labeled with a recommended maximum daily dose of 440 mg, and in package sizes of up to 6,600 mg) be granted unscheduled status

and

Naproxen sodium 220 mg per tablet (when sold in products labeled with a recommended maximum daily dose of 440 mg, and in package sizes exceeding 6,600 mg) remains in Schedule II.

Motion carried.

To be reported to NAPRA Executive Committee.

The Committee wished to communicate to NAPRA their concerns regarding current Health Canada product labeling standards for OTC analgesics and recommends drawing Health Canada's attention particularly around the language used on the product labeling. It is important to use simple language for contraindications and use common drug names rather than drug classes when describing drug interactions. The information has to be more explicit to enable a consumer to make an informed decision for self selection.

Finally, the Committee expressed concern regarding the current NDSscheduling of ibuprofen, particularly noting there are no limitations on conditions of sale based on package size. The Committee would be interested in revisiting the information on ibuprofen. In the context of a review of any NSAID, the Committee believes that consumer usage studies, particularly focussing on issues that may pertain to large package size, are necessary and should be made available by sponsors.

5.0 Business arising from previous meeting

5.1 Guidelines for Scheduling Status Submissions.

K.Vesterfelt reported that no further work had been done on this project but the guidelines would be re-examined during the forthcoming National Drug Schedule review. R. Wilson suggested that a brain storming session at a future NDSAC meeting on critical elements that are necessary in a manufacturer's submission for a scheduling status review be conducted.

5.2 Comparative OTC Scheduling Structure from other Jurisdictions.

K.Vesterfelt reported that no further work had been done on this project. The members noted that this had been discussed in the past and at minimum, OTC scheduling comparisons from OECD (Organizations for Economic Cooperation and Development) countries should be included in manufacturer's submissions.

6.0 Updates

6.1 Natural Health Products Regulation update

C Bouchard informed the Committee the Natural Health Products Unprocessed Licence Application Regulation had come into effect August 4, 2010, allowing natural health products that have been issued an exemption number, to be sold on the Canadian market. NAPRA has updated its Position Statement regarding the sale of non-approved marketed health products to include this group of natural health products.

6.2 Update on Influenza vaccines

C. Bouchard informed the Committee of a question regarding the National Drug Schedule placement of a new influenza vaccine that received its NOC from Health Canada in the summer of 2010.

After a series of discussions with NAPRA Executive Committee, a decision was taken to interpret the NDS Schedule II entry for Influenza vaccines to include all influenza vaccines at this time. This issue highlights the need to bring more clarity for some substances listed in the NDS and will be further addressed when a comprehensive review of the NDS model is undertaken over the next few years.

7.0 For Information

7.1 TPD update

Dr. R. Bose informed the Committee that Health Canada continues to monitor the activities of the United States and other regulatory agencies regarding acetaminophen. The information gathered will be assessed in a Canadian context, after which Health Canada may consider whether regulatory amendments would be required.

Dr. R. Bose indicated the transition to a Natural Product Number (NPN) for natural health products currently with a Drug Identification Number (DIN) continues to proceed well and most products are converted to NPNs.

Dr. R. Bose shared with the Committee that the consultation process on the 'Interim Policy Statement on Health Canada's Working Definition for Nanomaterials' is now closed. Comments and suggestions received during this consultation period are being considered and Health Canada will make available information to further clarify the use of this policy statement.

8.0 Other administrative issues

C. Bouchard informed the Committee that the NAPRA Expense Reimbursement and Honoraria policy for the NDSAC members had been reviewed. It is expected that after the NAPRA Board meeting in November, the updated policy will become effective. C. Bouchard clarified that travel time for Committee members is not reimbursed. Members attending meetings that are only one-half day in length will be reimbursed for a full day.

Committee members suggested that the NDSAC meetings could serve to discuss other relevant issues if the number of submissions to be reviewed allowed for this. An environmental scan of issues that might be of interest to the Committee members could be considered in the planning for future agenda items.

C. Bouchard thanked M. Priddle who was attending her last NDSAC meeting and expressed sincere appreciation for the long commitment and outstanding contributions of Ms. Priddle as an NDSAC member since 2003, and since 2006, Chair of NDSAC. As an out-going Chair, a small token was offered to M. Priddle to show NAPRA's appreciation.

9.0 Date of next meeting

Tentatively set for December 5-6, 2010.

10.0 Adjournment

The meeting was adjourned at 3:30 p.m. on Sunday, September 12, 2010.