

A meeting of the National Drug Scheduling Advisory Committee (NDSAC) was held on Sunday, March 6, 2011, at the Lord Elgin Hotel, Ottawa.

Participants

Committee members

Dr. Ruth Wilson, Chair; Kathy McInnes, Vice Chair; Kim Abbass; Gail Bradley; Dr. Nancy MacDonald; Dr. Sheldon Koven; Dr. Peter Zed; Dr. Carlo Marra

Observers

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

Staff

Carole Bouchard – NAPRA Executive Director
Kathy Vesterfelt – NAPRA, Manager, Professional and Regulatory Affairs, Committee Secretary

1.0 Call to order

1.1 Call to Order

Dr. Ruth Wilson called the session to order at 9:00 a.m. and welcomed everyone to the meeting. As the Chair was also welcoming a new member, Dr. Marra, she invited members and participants to introduce themselves and say a few words about their background.

1.2 Conflict of interest declarations

The Chair called for conflict of interest declarations. Dr. MacDonald indicated that she had worked for the company that had been granted Interested Party status. However, her employment with the company ended upon her retirement 7 years ago. The committee members did not feel that this represented a conflict of interest. No other members had anything to declare.

2.0 Approval of the agenda

The agenda was approved as circulated with the correction of the tentative date of the next meeting.

3.0 Approval of the minutes September 12, 2010 meeting

The minutes were approved as circulated electronically to Committee members and posted on the NAPRA website.

4.0 New Business

4.1 Reassessment of the request for a change in scheduling status of naproxen sodium 220mg per tablet (when sold in products labelled with a recommended maximum daily dose of 440 mg, and in package sizes exceeding 6,600 mg) to Unscheduled.

The Chair reviewed NAPRA's request to conduct a reassessment of the request for unscheduled status of Naproxen sodium 220 mg per tablet (when sold in products labelled with a recommended maximum daily dose of 440 mg, and in package sizes exceeding 6,600 mg). R. Wilson noted that additional information had been received from the Applicant pursuant to the previous

meeting. Further, an Interested Party (IP) status was granted to McNeil Consumer HealthCare. Information was also provided by the IP. No comment was received through the alternate method of participation. The committee reviewed the information received in addition to the content contained in the original submission by Bayer Inc. received for the September 2010 NDSAC meeting.

R. Wilson welcomed Todd Breedon, Jeannette Pringle and Janet Cameron, representing McNeil Consumer HealthCare, a division of Johnson and Johnson Inc., granted Interested Party status to the proceedings. The group made a presentation to the committee which was followed by a question and answer period.

Representatives of Bayer Inc. Consumer Care (the Applicant) made a presentation before the committee. Attending on behalf of Bayer Inc. Consumer Care were Leonard Baum, Joseph Chan and Neil Hamilton. The presentation was followed by a period of questions and answers with committee members.

The committee then reviewed and discussed the information previously submitted by the Applicant and the information received by the Interested Party, as well as both presentations.

The committee members noted that both the Applicant and Interested Party had provided consumer usage studies and acknowledged that this type of information was helpful to the committee in their deliberation, recognizing the challenges in study design, potential bias and differences in interpretation of results of such studies.

The Chair led the committee through a review of the applicability of this drug product in package sizes exceeding 6,600 mg to all scheduling factors. It was agreed that the same scheduling factors identified at the September 12, 2010 NDSAC meeting with the exception of Factor #II-9 remained applicable. (Those being Factors #I-4, #I-6, #II-2, #II-10, #III-2, #III-3 and #III-5). After further discussion, it was agreed that the applicability of these factors warranted placement in Schedule III.

The NDSAC opted for a cautious approach in formulating this recommendation. Although there is no specific data that speaks on how to apply the factors in the context of the appropriateness of product package size in relation to duration of use, the NDSAC members are of the opinion that they were consistent with the previous review of this substance and the recommendation is appropriate in the present situation; e.g. during the 2008 drug scheduling review of naproxen sodium 220 mg, some factors were not considered applicable in the context of a product package size for a short duration of use.

From the information the committee reviewed, the updated data indicates the incidence of reported serious adverse events remains stable and is low. The committee again noted the 4 fold difference between Canadian and Global adverse event data. An ongoing concern of committee members is the possibility of unreported or under reported adverse events seen with clinical experience as can occur with all NSAIDs, particularly in the elderly patient or those with co-morbid illnesses; for example worsening of hypertension or congestive heart failure.

The committee does not dispute the fact that the product was found to meet Health Canada's criteria to be on the Canadian market as an OTC product when used at maximum daily dose of 440 mg for a short duration of use. However, if the drug is not being used according to label instructions or is being used as a chronic therapy without appropriate monitoring, as may be enabled by larger package sizes, there may be an increased risk for serious adverse events. Again, the committee noted this would apply in principle to all OTC oral NSAIDs.

Although it is acknowledged that labelling for the OTC oral analgesics is under the purview of Health Canada, the NDSAC maintains their view that consumers may benefit if simple language for drug interactions and common drug names rather than drug class are used when describing drug interactions.

The NDSAC is of the opinion that naproxen sodium 220 mg per tablet is still relatively new to the Canadian consumer as an OTC product. Although definitions of "new" exist in a few Health Canada guidelines, this definition does not necessarily apply in this context. Other OTC oral NSAIDs were on the market for a considerably longer period of time before going to unscheduled status. The switch of this molecule from prescription to nonprescription includes a new strength (from prescription naproxen sodium) and a different dosage frequency than seen for other oral OTC analgesics. The committee maintains its overall conclusion that consumer experience using this product as an OTC product in the Canadian market is less extensive than other currently marketed oral analgesics.

Consumer usage and attitudinal studies provided to the Committee yielded conflicting results. It was not clearly evident to committee members from the information provided, what the actual patterns of consumer behaviour are when using this product.

When a substance is placed in Schedule II or Schedule III of the NDS, the committee noted that a consumer always has the option to obtain a larger package size of naproxen sodium 220 mg from a pharmacy. At the present while Canadian consumers may be less familiar with this OTC analgesic, Schedule III would continue providing a mechanism for the public to seek immediate advice from a pharmacist. This is particularly important for certain patient populations as previously mentioned.

It was moved by Dr. Marra, seconded by Dr. Zed that Naproxen sodium 220 mg per oral dosage unit (when sold in products labelled with a recommended maximum daily dose of 440 mg, and in package sizes exceeding 6,600 mg) be granted Schedule III status.

Motion carried.

To be reported to NAPRA Executive Committee.

5.0 Business arising from previous meeting

5.1 Guidelines for Schedule Status Submissions

Dr. Wilson requested that time be allotted at a future NDSAC meeting to brainstorm this issue.

6.0 Updates

6.1 Natural Health Products Regulations update – Carole Bouchard

Ms. Bouchard provided an update with respect to the delay in Health Canada's implementation date of the compliance and enforcement policy for both the *Natural Health Products Regulations* and the recent *Unprocessed Product Licence Applications Regulations*. Ms. Bouchard mentioned again to the Committee members that NAPRA was reviewing its Natural Health Products Policy which was approved in 2006.

7.0 For information

7.1 TPD update – Dr. R. Bose

Dr. R. Bose informed the Committee that Health Canada continues to have regular communications with the United States and other regulatory agencies regarding acetaminophen. On Jan. 13, 2011, FDA announced it is asking all makers of prescription products that contain acetaminophen to limit the amount of the drug to 325 milligrams per tablet or capsule. The FDA also is requiring manufacturers to update labels of all prescription combination acetaminophen products to warn of the potential risk for severe liver injury. Health Canada is also actively evaluating Canada-based information or data streams related to paediatric acetaminophen product use and safety considerations.

Dr. R. Bose shared with the Committee the study requirements for Rx to OTC SWITCH submissions, in order to ensure safety of such drug products in an OTC setting.

8.0 Other Administrative issues

Ms. Bouchard brought to the Committee members' attention that the updated NAPRA Expense Reimbursement and Honoraria policy was now in effect.

9.0 Date of next meeting

Tentatively set for June 12-13, 2011.

10.0 Adjournment

The meeting was adjourned at 3:15 p.m. on Sunday, March 6, 2011.