

A meeting of the National Drug Scheduling Advisory Committee (NDSAC) was held on Sunday evening, June 8 and Monday, June 9 2008 at the Lord Elgin Hotel, Ottawa.

Participants

Committee members

Margot Priddle, Chair; Dawn Frail, Vice Chair; Kim Abbass; Dr. Sheldon Koven, Dr. Larry Lynd; Dr. Ruth Wilson; Dr. Peter Zed

Observers

Don Hoffman – Therapeutic Products Directorate, Health Canada (for Monday portion only)
Joan Sayer – Consumers Association of Canada

Staff

Norma Lynn Pearson – NDSAC resource and pharmacist, Ottawa Valley Regional Drug Information Centre
Barbara Wells –NDSAC Consultant and Committee Secretary

Regrets

Dr. Nancy MacDonald

1.0 Call to order

1.1 Call to Order

Margot Priddle called the session to order at 6:40 pm on Sunday evening, and welcomed everyone to the meeting.

1.2 Conflict of interest declarations

Ms. Priddle called for conflict of interest declarations. None were declared and all participants submitted signed conflict of interest declarations.

2.0 Approval of the agenda

The agenda was approved as circulated.

3.0 Approval of the minutes of the April 6-7 2008 meeting

Draft minutes were previously circulated and approved electronically. In response to a request from the Chair, Ms. Wells indicated that the outcome of a brief teleconference call meeting held April 21, 2008 regarding levonorgestrel be documented and circulated to the committee.

4.0 Business from previous meetings

4.1 "Parenteral nutrition" vs "total parenteral nutrition"

The Committee reviewed materials submitted by the Canadian Association of Naturopathic Doctors (CAND) pursuant to the December 2007 meeting.

There was discussion about the possible impact that Bill C-51 might have on the ability of naturopaths to order or prescribe some nutritional therapies for parenteral use, currently in Schedule I. Ms. Wells reported that a copy of the original 1995 National Drug Schedule document could not be located to determine the intent of this scheduling.

It was agreed that Ms. Wells would follow-up with CAND regarding the possible impact of Bill C-51 and pending this outcome, Ms. Pearson and Ms. Wells will develop a briefing document for presentation to the committee at the next meeting.

4.2 Guidelines for Scheduling Status Submissions

Ms. Wells reported that the guidelines would be posted on the NAPRA website as soon as possible, and stakeholders would be notified of this resource.

The matter of conducting scheduling reviews before a "Notice of Compliance" is granted was discussed. Occasionally, a company will request a scheduling recommendation from the committee while waiting for completion of NOC processing by Health Canada, in order to shorten the Rx-to-OTC switch time. The committee discussed the implications of these situations; namely the uncertainty caused when scheduling recommendations are made on a conditional basis (i.e. without having the benefit of Health Canada's final assessment). There was general agreement that this could have ramifications on the quality of the recommendations, and therefore pre-NOC scheduling deliberations should no longer be permitted.

It was moved by D. Frail, seconded by L. Lynd that NDSAC institute a policy whereby scheduling requests will not be considered unless a Notice of Compliance has been granted for the product.

Motion carried.

To be reported to NAPRA Council for approval.

Dr. Wilson spoke on a related matter, the issue of background and resource materials made available to the committee. There was agreement with Dr. Wilson's suggestion that the committee be provided with a reference chart showing the drug scheduling structure in similar jurisdictions (e.g. US, UK, AU, NZ, EU) expressed in terms of Schedules I, II, III and unscheduled. Dr. Lynd pointed out that the new submission guidelines speak to the need for applicants to report on the scheduling status of the drug under review in various jurisdictions, and there was agreement that a table template (identifying the jurisdictions of interest and how the conditions of sale are to be expressed) should be included in guidelines. Ms. Wells agreed to follow-up.

5.0 New business

5.1 Scheduling request for naproxen sodium

Bayer Consumer Products applied for unscheduled status for naproxen sodium in 220 mg per oral dosage unit, pending exemption from federal Schedule F. Two pharmaceutical companies, Wyeth Consumer Healthcare and McNeil Consumer Healthcare were granted Interested Party status for this review; both Parties opposed to unscheduled status for naproxen sodium.

At 9:00 am on Monday, the committee reviewed and discussed the information previously submitted by the Applicant and Interested Parties. The committee welcomed Narinder Grewal and Murray Brown, representing Wyeth Consumer Healthcare, to the meeting at 10:00 am, and they made a presentation to the committee. This was followed by a presentation by Todd Breedon and Jeannette Pringle, representing McNeil Consumer Healthcare, at 11:00 am. Michele Kay, Steve Zlotnick, and Birte Petersen, representing the Applicant, then made a presentation at 12:30 pm. There was a brief question-and-answer period after each presentation.

Following the presentations and attendances by the Applicant and Interested Parties, the committee reviewed the materials and information at hand. It was noted that during the Bayer presentation some information had been referred to that the committee did not previously have, namely:

- an unpublished study (or abstract) regarding interactions between low dose ASA and naproxen, and
- a Cochrane Collaboration review comparing acetaminophen with naproxen

Also, a study by Temple et al was referred to, and although it was accessed on-line during the meeting, there had not been sufficient time for the committee members to review it. It was agreed that Ms. Wells would request this information from Bayer and forward it to committee members for consideration.

Ms Priddle then led the committee through a preliminary review of the applicability of all scheduling factors to this drug. It was agreed that scheduling factors #I-4, II-9, #III-1, 2, 4, 5, 6, and 7, were applicable. Factors # II-10 and III- 9 were determined to not be applicable, providing that product package size was appropriate in relation to duration of use. There was a significant amount of discussion on this last point, regarding package sizes for naproxen sodium in light of the limited amount of experience in Canada as a non-prescription drug. There was agreement that, pending the outcome of reviewing the identified missing documents and a follow-up discussion by teleconference, the committee would recommend:

- Schedule III status for naproxen sodium (when sold in products labelled with a recommended maximum daily dose of no more than 440 mg, and in package sizes of up to 6,600 mg.)
- Schedule II status for naproxen sodium (when sold in products labelled with a recommended maximum daily dose of no more than 440 mg and in package sizes exceeding 6,600 mg).

It was agreed that Ms. Wells would contact Bayer for the identified documents, and that the committee would meet by teleconference to discuss this information and finalize the recommendations at 10:00 am EST on July 16th.

5.2 Election of Chair, Vice-Chair for 2008-09

Ms. Priddle noted that her second term as committee Chair would be ending in June and that with the end of Ms. Frail's appointment on the committee, a replacement Vice-Chair would also be needed.

She asked for nominations to these positions and there was considerable discussion about responsibilities and time commitment required. At the request of the Chair, Ms. Wells facilitated this section of the agenda.

Vice-Chair

It was moved by D. Frail, seconded by P. Zed, that Ruth Wilson serve as NDSAC Vice-Chair, for the 2008-2009 term.

Motion carried.

Chair

Committee members asked if Ms. Priddle would consider remaining for another term as Chair. She said that she was hesitant to do so because of the increasing time commitment required. Ms. Priddle indicated that the past two-three months had been particularly time-consuming for the Vice Chair and herself, due to the need to adjudicate many Applicant-Interested Party interchanges. Ms. Wells vouched for the recent time commitments required of the Chair and Vice Chair, due to various issues associated with committee business that had not previously been the norm. There was further discussion, and Ms. Priddle agreed to remain as Chair.

It was moved by S. Koven, seconded by L. Lynd that Margot Priddle continue to serve as NDSAC Chair, for the 2008-09 term.

Motion carried.

Both motions to be reported to NAPRA.

6.0 For information

6.1 Therapeutics Products Directorate (TPD) update

Mr. Hoffman provided a brief verbal update on a number of matters of interest.

6.2 Status of new member recruitment

Ms. Wells reported that a new member had been recruited to replace Dr. Lynd's position, but that a search was continuing to replace Ms. Frail's position.

7.0 Other matters

Ms. Sayer expressed her appreciation for the support that the committee receives from the NAPRA office; in particular Lynn Rush has been very helpful in ensuring that she receives meeting materials.

Ms. Wells and Ms. Priddle both paid tribute to Dr. Lynd's very significant contribution to the committee over the past six years, as this meeting represented the end of his term of office.

8.0 Date of next meeting

A teleconference meeting regarding naproxen has been scheduled for Wednesday, July 16th, 2008.

The next face-to-face meeting of the committee has been tentatively scheduled for September 14-15, 2008. Deadline for receipt of submissions is July 16.

9.0 Adjournment

The meeting was adjourned at approximately 3:15 pm on Monday.