

Minutes of the National Drug Scheduling Advisory Committee Meeting September 16-17, 2007

A meeting of the National Drug Scheduling Advisory Committee (NDSAC) was held on Sunday, September 16 and Monday, September 17, 2007 at the Lord Elgin Hotel, 100 Elgin Street, Ottawa.

Participants

NDSAC Members	Margot Priddle (Chair), Dawn Frail (Vice-Chair), Dr. Sheldon Koven, Dr. Larry Lynd, Dr. Nancy MacDonald, Dr. Ruth Wilson
Observers	Don Hoffman – Health Canada; Joan Sayer – Consumers Association of Canada
Staff	Karen Wolfe – Executive Director, NAPRA; Dina MacLeod – Ottawa Valley Regional Drug Information Service; Barbara Wells – Consultant and NDSAC Secretariat

Guests

Paladin Labs	Dr. Patrice Larose, Dr. Colleen Metge, Dr. Sheila Dunn Ferouk Rehan (observer)
Wyeth	Dr. Murray Brown, Narinder Grewal

1.0 Call to Order, Opening Remarks and Conflict of Interest Declarations

Ms. Priddle called the meeting to order at 9:05 am. She introduced Dina MacLeod, a drug information pharmacist replacing Norma Lynn Pearson for this particular meeting, and Barbara Wells, also a pharmacist. Ms. Wells was very recently contracted by NAPRA to assist with NDSAC Secretariat duties.

Ms. Wolfe provided an update on the recruitment of new NDSAC members, to replace Phil Hudson (term expiration) and Dr. Anita Carrie (resignation due to change in employment). She indicated that the goal was to have these two positions replaced by the end of the month.

The Chair called for Committee members to declare any real or perceived conflicts of interest. Dr. Wilson indicated that she had previously served on the Ontario Women's Health Council and had recently been lobbied regarding the levonorgestrel scheduling matter to be considered at this meeting. Dr. MacDonald noted that during her past employment she had been involved with the non-prescription scheduling of ibuprofen, but there had been no contact with the company with regards to the matter to be considered at this meeting. The Committee evaluated these disclosures and agreed that they did not present conflict of interest problems.

2.0 Approval of the Agenda

The Committee agreed with the agenda as circulated.

3.0 Approval of the Minutes of the June 10-11, 2007 Meeting

Ms. Wolfe noted that these minutes had been approved prior to posting on the NAPRA website, and that the draft minutes of the teleconference call meeting held August 24, 2007 regarding Interested Party status would soon be circulated.

4.0 Business from the Previous Meeting

4.1 Rules of Procedure and IP Status

The Committee discussed the process by which interested parties were granted standing for matters under consideration at the meeting, as well as how unsuccessful IP applications were processed. A timeline for each of the drugs under review was circulated, showing the dates on which IP applications were received and subsequently processed.

It was agreed that policy was needed to streamline and standardize the manner by which *non-IP* submissions are processed and circulated to committee members. It would be important to ensure that committee members are made aware of information and comments from stakeholders, without being deluged with form letters or other outcomes of widespread lobbying. There was support for a suggestion made by Ms. Frail that the names of individuals and organizations contacting NAPRA regarding scheduling matters be automatically added to the "Drug Scheduling External Liaison Group" (DSELG), to alert as many stakeholders as possible about upcoming drug scheduling reviews.

Action: Staff to further develop the rules of procedure to address the processing of non-IP sources of information and comment, and that policy be developed to ensure that the DSELG e-mail alert subscription list be as broad as possible to ensure that stakeholders are kept informed about upcoming NDSAC matters.

4.2 Scheduling Review of Parenteral Bupivacaine

At the invitation of the Chair, Ms. Wells outlined the rationale provided by the Manitoba Pharmaceutical Association for the request to review the current Schedule II status of parenteral bupivacaine. The justification for and implications of launching such a review were discussed, as well as the possible option available to the applicant to move the drug into Schedule I at the provincial level.

Action: Staff to outline options available to the applicant to move this matter forward: full review sponsored by MPhA, full review sponsored by NAPRA, or provincial scheduling on an exception basis.

4.3 Clarification of "parenteral" nutrition vs "total parenteral" nutrition

This matter was deferred to the next meeting, pending receipt of additional information from the Ontario Naturopaths Association.

4.4 Revision of Scheduling Factors

Ms. Wolfe reminded the committee that the original consultation on the proposed revised scheduling factors had been suspended, due to the need to provide stakeholders with more context for the revisions. A former member of NDSAC, Dr. Jeff Taylor, who had been instrumental in developing the revisions, recently reviewed the final proposed changes and provided comment. Ms. Wolfe predicted that the revised document would be

ready for external circulation around the end of September, with a 60-day review period for feedback.

Action: Staff to finalize revised scheduling factor consultation document and circulate for comment. Results to be considered at next meeting.

4.5 Guidelines for Scheduling Request Submissions

Ms. Wells reported that the "Guidelines for Scheduling Status Submissions for Review by the National Drug Scheduling Advisory Committee" document was currently being edited and formatted. She noted that the final draft would be circulated to the committee as soon as possible (within next 48 hours) for approval.

Action: Staff to finalize Guidelines document and circulate final draft to committee for approval.

5.0 New Business

5.1 Scheduling Request for Levonorgestrel 0.75 and 1.5 mg

This matter pertains to Paladin Lab's request to re-schedule levonoregstrel 0.75 from its current Schedule II status to Schedule III and to grant levonorgestrel 1.50 mg Schedule III status, pending its removal from federal Schedule F.

The committee reviewed the submission from Paladin Labs, material and interrogatories submitted by the three Interested Parties (Alberta College of Pharmacists, Canadian Association of Chain Drug Stores, and Ontario Pharmacists Association) and the Paladin response to these interrogatories, as well as information and comment from a wide range of interested stakeholders.

It was noted that while Paladin Labs would be presenting to the committee, none of the Interested Parties had accepted invitations to make presentations at the meeting.

The Chair welcomed the Paladin Lab representatives to the meeting at 1:00 pm. A brief presentation was given by Dr. Larose, Dr. Dunn and Dr. Metge, followed by a question-and-answer session. This session with the applicant ended at approximately 2:00 pm.

There was a great deal of discussion about many aspects of the use of levonorgestrel as emergency contraception, with a particular focus on the impact that pharmacists' interventions and product labelling have on appropriate product selection and use. Committee members were concerned about the fact that the proposed product packaging was configured in such a way that important pieces of information were obscured from the view of patients seeking to self-select.

There was discussion about Health Canada's original decision to remove levonorgestrel 0.75 from Schedule F. It was noted that the NDSAC decision had been referred to in Health Canada's "Regulatory Impact Analysis Statement" (RIAS), which would appear to indicate that the recommended place of sale had been factored into the government's decision to remove the drug from prescription status federally.

Actions:

The Applicant and Interested Parties will be asked to provide more information on patient product selection related to the safe and effective use of this drug. In particular, the committee is interested in the need for and/or impact of, pharmacists' interventions in the appropriate use of levonorgestrel as an emergency contraception, with particular focus on

the under-18 patient group. The Committee requested further information on the proposed labelling and packaging of this product should it be available on Schedule III.

Further to discussion of the Committee, Mr. Hoffman will take back and route internally in Health Canada a request for an opportunity for clarification/dialogue, given a Canada Gazette proposed amendment for the 1.5 mg levonorgestrel dosage strength had not yet been published at the time of the meeting.

It was moved by D. Frail, seconded by S. Koven that "the scheduling of levonorgestrel 0.75 and 1.5 mg be deferred until additional information on patient product selection related to the safe and effective use of this drug is obtained and further, that this information be obtained in time to be considered by the committee at the March 2008 meeting".

Motion carried.

5.2 Scheduling Request for Ibuprofen 400mg

This matter pertains to Wyeth Consumer Healthcare's request to re-schedule ibuprofen 400 mg from its current Schedule III status to Unscheduled.

The committee reviewed the submission from Wyeth, as well as material and interrogatories submitted by the Canadian Association of Chain Drug Stores, the Interested Party in this matter.

It was noted that Wyeth would be presenting to the committee, whereas the Interested Party had declined to make a presentation at the meeting.

The Chair welcomed the Wyeth representatives to the meeting at 10:00 am on Monday. A brief presentation was given by Mr. Grewal and Dr. Brown, followed by a question-and-answer session. This session with the applicant ended at approximately 11:00 am.

After some discussion, the committee agreed that the following scheduling factors were applicable to ibuprofen 400 mg: Schedule I- Factor #4; Schedule III – Factors #1, 2, 4. It was further agreed that these factors were not considered to be sufficient to retain this drug in Schedule III.

It was moved by R. Wilson, seconded by L. Lynd that "ibuprofen and its salts in strengths of 400 mg or less per oral dosage unit" be Unscheduled.

Motion carried.

6.0 For Information

6.1 Therapeutic Products Directorate Update

Mr. Hoffman provided an update on recent TPD appointments and public consultations underway.

7.0 Date of Next Meeting

Ms. Wolfe announced that there was no indication as yet that the committee would need to meet in December (as tentatively scheduled). It was agreed that the committee members would be surveyed as to preferences for the 2008 meeting schedule.

8.0 Adjournment

The meeting was adjourned at 12:00 noon.