

**Minutes of the National Drug Scheduling Advisory Committee Meeting
March 26-27, 2006**

A meeting of the National Drug Scheduling Advisory Committee (NDSAC) was held on Sunday and Monday, March 26/27, 2006 at the Lord Elgin Hotel, 100 Elgin St., Ottawa.

Participants:

NDSAC Members: Dr. Jeff Taylor (Chair; March 26 only), Dr. Mark Armstrong (Vice-Chair), Dawn Frail, Phil Hudson, Dr. Larry Lynd, Margot Priddle, Fred Rumpel

Observers: Micheline Ho, Joan Sayer

Staff: Norma Lynn Pearson (Acting Drug Information Specialist, Ottawa Valley Regional Drug Information Centre), Ken Potvin (Executive Director, NAPRA)

Regrets: Dr. Ruth Wilson

Guests: **Pfizer Consumer Healthcare:** Praveen Chawla (Director, Regulatory Affairs), K. Jill Grande (Manager Regulatory Affairs), Jeannette Pringle (Manager, Regulatory Affairs)
Natural Health Products Directorate: Sameena A. Khan (Policy Analyst, Bureau of Policy Development and Regulatory Affairs), Dr. Robin Marles (Director, Bureau of Clinical Trials and Health Science)
Therapeutic Products Directorate: Brigitte Zirger (Director, Policy Bureau)

1.0 Call to Order and Opening Remarks

Dr. Taylor called the meeting to order at 9:05 am on Sunday March 26th and thanked all participants for taking the time out of their busy schedules to be at this meeting.

Dr. Ruth Wilson, NDSAC's newest member, had sent regrets for her absence due to a prior commitment overseas.

1.1 Conflict of Interest Declarations

Dr. Taylor called for Committee members to declare any real or perceived conflicts of interest. Dr. Lynd reported that he is expecting to receive a 'grant in aid' for the study of NSAIDs and Cox-2 Inhibitors, from Pfizer. This has been approved, and is imminent pending finalization of a contract. In the interest of ensuring that there was no perceived conflict of interest, Dr. Lynd agreed to exclude himself from deliberations and voting on the drug scheduling reviews submitted by Pfizer for this meeting.

2.0 Approval of the Agenda

On a motion by M. Armstrong, the Agenda was adopted as circulated.

3.0 Noting Approval of the Minutes of the December 2005 NDSAC Meeting

K. Potvin noted that the Minutes from the December 2005 NDSAC meeting had been approved by electronic survey of the meeting attendees, and had been subsequently posted on the National Association of Pharmacy Regulatory Authorities (NAPRA) website.

4.0 Business from Previous Meetings

4.1 Committee Membership

K. Potvin reported that the following membership changes had occurred since the last NDSAC meeting:

- Dr. Ruth Wilson has replaced Dr. Marilyn Caughlin
- Fred Rumpel has changed employment from Biomira Inc. to the Alberta Government, in the Pharmaceutical Policy and Programs area; it was agreed by the Members that NAPRA would be advised to commence a search for a replacement representative from the pharmaceutical industry sector
- Dr. Mark Armstrong is attending what is likely to be his last meeting, since his second three year term on NDSAC is now completed. A call for nominees has gone out for a replacement.
- Norma Lynn Pearson has replaced Denis Belanger in providing support services from the Ottawa Valley Regional Drug Information Service (OVRDIS)

Dr. Armstrong's contributions to NDSAC over the past six years were recognized with appreciation from the Chair on behalf of the Committee, and he acknowledged that he would be willing to serve as an alternate per the recently approved policy. Recruitment will also commence regarding a replacement for Dr. Taylor, who is nearing the end of his term with NDSAC.

4.2 Drug Scheduling Decision on Ephedrine/Pseudoephedrine

K. Potvin provided a status update on the implementation of the changes to the National Drug Schedules at the provincial/territorial level with respect to ephedrine and pseudoephedrine. A table is posted on the NAPRA website that provides summary information. There are a number of unanswered questions about whether/how the scheduling changes apply to approved Natural Health Products (NHPs) with these medicinal ingredients, and what the monitoring and enforcement practices might be.

4.3 “Schedule F Recommended”

K. Potvin noted the significant progress that had been made in bringing forward a draft policy to deal with the “Schedule F Recommended Drugs” dilemma, whereby products receive market authorization with the intent of being handled as prescription drugs, in advance of their official inclusion in Schedule F to the *Food & Drug Regulations*. The external stakeholder consultation on the draft policy was overwhelmingly positive, and virtually all of the suggestions received were incorporated into the revised version. Health Canada staff are working on the procedures regarding notification of NAPRA and non-Member pharmacy regulatory authorities regarding new products that receive a Notice of Compliance (NOC) with “Schedule F Recommended” status. There are currently approximately 70 medicinal ingredients with this status. It is expected that the policy will be finalized and approved at the April 23, 2006 NAPRA Board meeting.

An amendment to the wording in the *Intent* section of the document was recommended by the Committee and will be incorporated into the revised version brought before the Board.

4.4 Definition of “Marketed for”

K. Potvin presented a draft definition of “marketed for”, for discussion by NDSAC. The Committee suggested the removal of “professional” in front of “promotional material”, as well as a review of the definition by both NAPRA’s Executive Committee (EC) and legal counsel prior to the external consultation through the Drug Scheduling External Liaison Group.

4.5 NAPRA Response to Health Canada Letter re: Ibuprofen

It was reported by K. Potvin that the Directors General of both the Therapeutic Products Directorate (TPD) and Marketed Health Products Directorate (MHPD) had received letters from NAPRA in response to the invitation to address the comments made by the Expert Advisory Panel on Cox-2 Inhibitors. No response to the letters has been received. M. Ho indicated that Health Canada is continuing work on revising its guideline for NSAIDS and corresponding information for the consumer.

5.0 New Business

5.1 Election of Chair, Vice-Chair for 2006-07

F. Rumpel nominated Dr. Jeff Taylor to serve as Chair for 2006-07. Dr. Taylor declined the nomination, as he has reached the end of the standard term of eligibility with the Committee.

F. Rumpel nominated Margot Priddle to serve as Chair, and Dawn Frail as Vice-Chair, for the 2006-07 year, commencing at the close of the June 2006 meeting. The nominees accepted and were acclaimed into their respective positions.

5.2 Nicorette (Nicotine) Lozenge (4 mg or less): Request for Unscheduled Status

J. Pringle and P. Chawla made a 15 minute presentation (10:50 – 11:05) on behalf of Pfizer Consumer Healthcare in support of their request for Unscheduled status for nicotine lozenges (4 mg or less), pending federal deregulation from Schedule F. This was followed by a question and answer period. The Pfizer representatives reported that they had received confirmation from Health Canada that the nicotine replacement products will be regulated as NHPs, within the transition period ending December 2009.

In subsequent discussion in the afternoon, NDSAC Members agreed that the following scheduling factors were applicable: Schedule III, Factors #2, #4, #5, and #6.

It was moved by M. Armstrong that Nicotine and its salts (when sold in a form to be administered orally as a lozenge containing 4 mg or less of nicotine per lozenge) be assigned to Unscheduled status. Motion carried.

It was noted that the Unscheduled status is pending final amendment of Part I of Schedule F to the Food and Drug Regulations to remove these nicotine oral lozenges from prescription status.

5.3 Diphenhydramine and its salts and preparations for topical use: Request for Sch. III Status

J. Grande and P. Chawla made a 15 minute presentation (11:20 – 11:35) in support of Pfizer Consumer Healthcare's request for the move of diphenhydramine and its salts and preparations for topical use from Schedule II to Schedule III. This was followed by a question and answer period. A significant focus of the discussion was on the label warnings and how these are likely to be understood or interpreted by patients. The current labeling includes the warnings "do not apply to blistered, raw and oozing areas", as well as "do not use on extensive areas of the skin". The Committee felt that these label warnings were sufficient to mitigate the risks of inappropriate use on chicken pox lesions, that has been associated with adverse event reports in the literature.

During the NDSAC's deliberations on the Scheduling Factors it was noted that the information submitted by Pfizer was based on a 2% concentration, so there was agreement that the scheduling decision would be based on that strength. The Committee agreed that the following scheduling factors were applicable: Schedule III, Factors #1, #2, #3, #5, and #6. The current labeling was felt to be sufficient to address any Schedule II Factors that were previously assessed as applicable (specifically #7 and #8).

It was moved by M. Priddle that diphenhydramine and its salts and preparations (for topical use in concentrations of 2% or less) be moved to Schedule III. Motion carried.

5.4 Review of Scheduling Factors

J. Taylor opened the discussion on the review of the Scheduling Factors, noting that this matter has been a work-in-progress since the summer of 2002. There was considerable debate about terminology and the scope of the Schedules in terms of the breadth of health care practitioners. Significant time was spent on refining the Scheduling Factors wording, in an attempt to make it simpler, more definable, and with less redundancy. The draft document will be revised pursuant to the decisions made by the Committee, and a revised version will be pilot-tested in parallel with the current Scheduling Factors over the next couple of NDSAC meetings. The ultimate revised draft will be submitted to NAPRA for comments, and then disseminated for external consultation.

The Committee adjourned for the day at 5:15 pm on Sunday March 26th.

As the Chair was absent for the second day of the meeting, Vice-Chair M. Armstrong called the meeting back to order at 9:00 am on Monday March 27th and welcomed the guests from Health Canada.

5.5 Natural Health Products and the National Drug Schedules

Representatives from the Natural Health Products Directorate (NHPD) and TPD participated in discussions with NDSAC on the implications of the National Drug Schedules (NDS) vis-à-vis NHPs. Dr. Marles delivered a presentation to serve as a background for the discussion. S. Khan reported on the intent and status of the “OTC” or “self-care” amendment that is under consideration. Issues of monitoring and enforcement were a key part of the discussion when considering how/if the NDS should apply to NHPs. There was an excellent exchange of information, and unanimous agreement that the complex issues of this topic require continued communication between Health Canada and NAPRA.

5.7 Scheduling of Fluoride Products

With Health Canada officials present, the potential for scheduling of fluoride products in oral preparations for topical administration was discussed. It was noted that NHPs that are designated as “Professional Use Only” currently fall under the *NHP Regulations* because they are not otherwise covered by the *Food & Drug Regulations (F&DR)*, and that both TPD and NHPD are using the same labeling standards. If the “OTC amendment” becomes reality, “Professional Use Only” products would likely be regulated under the *F&DR*.

N.L. Pearson offered details on the background work undertaken to prepare the NDSAC Deliberation Document [0601], and observable “bands” of fluoride ion concentration in terms of products available in Canada.

The next steps that were agreed to in terms of potentially scheduling these fluoride products were: draft a recommendation for Schedule status based on the current Labeling Standards; meet with interested stakeholders in advance of the next meeting to get early reaction to the proposal; and put the matter on the agenda of the June 11/12 meeting for further deliberation and a possible scheduling recommendation.

5.8 NAPRA Response to TPD Project No. 1474

K. Potvin informed the Committee that NAPRA had submitted comments to Health Canada in regard to Project No. 1474, and that the comments were available upon request.

5.9 Overview of TPD Organizational Changes

M. Ho provided an update on the organizational changes with the TPD. The former Senior Medical Advisor Bureau (SMAB) has been dismantled, a special Bureau has been established for Clinical Trials, and an Office of Risk Management has been created. Further details are available from M. Ho or K. Potvin.

5.10 TPD Proposal to add 3 ingredients to Part I of Schedule F: atomoxetine and its salts; escitalopram and its salts; and omalizumab (Project 1449)

For information only.

5.11 TPD Proposal to add 2 ingredients to Part I of Schedule F: paricalcitol; and pegaptanib and its salts (Project 1463)

For information only.

5.12 TPD Proposal to add tramadol and its salts to Part I of Schedule F (Project 1490)

For information only.

6.0 Other Business

6.1 Capacity for NDSAC Meetings, and Handling of Excess Submissions

As NAPRA received more drug scheduling review submissions for this particular meeting than it could handle within the allocated meeting time, there was need for a discussion on how NAPRA should handle such situations in the future. There was general agreement that the submissions should be addressed in the sequence in which they are received by NAPRA, while

reserving the authority to change the sequence if it is determined to be in the public interest to do so (e.g. perhaps for new medicinal ingredients that have not been reviewed by NDSAC in the past). Any decision to deviate from the normal sequence would be determined jointly by the Chair of NDSAC and Executive Director of NAPRA, in consultation with NAPRA's Executive Committee as needed. If NAPRA agrees with this proposal, then external stakeholders will be notified. If there is an ongoing situation where reviews cannot be handled in a timely manner, then the capacity of NDSAC (e.g. number or duration of meetings) will be reassessed.

6.2 Policy #9604: Expense Reimbursement & Honoraria for NDSAC Members/Observers

The Executive Committee of NAPRA had invited comments from NDSAC on the draft revised Expense Reimbursement & Honoraria Policy. The issue of compensation for travel time was raised, and will be brought back to NAPRA for further consideration.

6.3 Other

a) Ibuprofen Topical Compounding

A question was posed by a Member about the compounding of topical ibuprofen cream, and whether this would be impacted by the schedule status of ibuprofen products in the NDS, in regard to any possible requirement for a prescription. The discussion focused on the use of ibuprofen as an active pharmaceutical ingredient (API) versus oral ibuprofen products listed in the NDS. There was general agreement that compounding of products is within the scope of pharmacy practice and that a prescription would not be required for nonprescription APIs, but that interpretations would be made by the provincial/ territorial pharmacy regulatory authorities.

b) Content of Submissions

The possibility of improving the content of the drug review submissions that NAPRA receives, by referencing requirements established by other organizations for similar purposes, was raised. L. Lynd offered to summarize the CIOMS Working Group 4 developments in creating a template for benefit-risk analysis, for consideration by NDSAC.

c) Format Options for Drug Scheduling Review Submissions

The possibility of receiving drug review submissions in electronic format was put forth for discussion. There are a number of alternate methods (e.g. password-coded CD's; secure website access for downloading). K. Potvin will conduct a survey of NDSAC Members to get input on their preferred option(s).

7.0 Date of Next Meeting

The next meeting of NDSAC will take place on Sunday June 11th/Monday June 12th, 2006.

8.0 Closing Comments and Adjournment

The meeting adjourned at 1:30 pm on Monday afternoon.

Recorder: Ken Potvin