

A special meeting of the National Drug Scheduling Advisory Committee was held at the Delta Chelsea Hotel, Toronto on February 15-16th, 2004.

Participating

Committee Members: Dr. Marilyn Caughlin (Chairman), Dr. Jeff Taylor (Vice Chairman), Dr. Mark Armstrong, Dawn Frail, Phil Hudson, Dr. Larry Lynd, Margot Priddle, Fred Rumpel

Committee Resource: Michelline Ho, Therapeutic Products Directorate, Health Canada

Committee Secretariat: Barbara Wells, Executive Director, NAPRA

Observer: Joan Sayer, representing the Consumers Association of Canada

Guests (presenting during the meeting): see page 3

1. Chair's Opening Remarks

Dr. Caughlin welcomed everyone to the meeting at 9:00 am. No conflicts of interest were declared.

2. Approval of the minutes of the December 7-8th, 2003 meeting

Ms. Frail asked for clarification of a portion of the minutes regarding the information provided to the committee from NAPRA about drug and health issues in general. After some discussion, it was confirmed that to reduce information overload for Committee members, the Executive Director should continue to use her own judgment about selecting materials for circulation.

It was then moved by M. Armstrong, seconded by P. Hudson that the minutes of the meeting of December 7-8th, 2003 be adopted as circulated. Motion carried.

3. Approval of the agenda

Dr. Caughlin then called for additions to the agenda. Ms. Wells suggested that a request just received from the Therapeutic Products Directorate regarding patient registry systems, be added under Other Matters, and this was agreed to.

The Chairman also cautioned that it was possible that there would not be time to discuss Agenda items # 4.2 and #4.3, pertaining to committee promotional and administrative matters, due to the tight presentation schedule.

It was then moved by D. Frail, seconded by J. Taylor that the agenda be adopted as amended. Motion carried.

4. Business

4.1 Review of the National Drug Schedules Structure

The Chairman announced that 14 presentations would be heard over Sunday and Monday, and the intent was primarily to provide feedback to the Committee on three focused questions:

- What changes do you expect to see in Canadian health care over the next 10 years?
- What are the strengths and weaknesses of the current three-schedule/four category drug-scheduling model?
- How might the current drug-scheduling model be improved to better serve the Canadian public?

Dr. Taylor led the Committee's review of the literature that had been previously circulated, followed with some discussion about the format of the presentations, the question-and-answer period, and style of the resulting report back to the Council of Pharmacy Registrars of Canada on the findings.

Following the presentations, Ms. Wells agreed to prepare a draft report for circulation to the Committee.

4.2 Administration

It was agreed that the matters planned for discussion regarding administration of the drug scheduling system would be deferred to the next meeting due to time constraints.

4.3 Promotion

It was agreed that the matters planned for discussion regarding promotion of the drug scheduling system would be deferred to the next meeting, due to time constraints.

5. **Other Matters**

5.1 Acetaminophen

As requested by the Council of Pharmacy Registrars of Canada, the Committee considered information and announcements from the US Food and Drug Administration regarding public safety campaigns about to be launched in the US to warn consumers about inadvertently exceeding the doses of OTC analgesics. There was discussion about the differences in the distribution of drugs between the US and Canada, and it was agreed that until evidence would suggest otherwise, there was no rationale to justify increasing restrictions on the sale of acetaminophen, ASA or ibuprofen in Canada, or on imposing additional labeling requirements on prescriptions.

5.2 Feasibility of developing a national drug/patient monitoring system

Ms. Wells outlined a request for assistance recently received from the Director, Bureau of Cardiology, Allergy & Neurological Sciences of the Therapeutic Products Directorate. The preliminary inquiry was whether or not NDSAC (or individual members of NDSAC) would be interested in assisting the Directorate in assessing proposed components of national monitoring system for patients using a particular drug. This drug, being considered now for approval to be marketed in Canada, requires monitoring due to its potential for diversion as well as its narrow therapeutic index (there have been reports of deaths in other jurisdictions due to overdose). Building on lessons learned from their experience with clozapine, it was hoped that the Committee could help identify and explore options for implementing a monitoring system that would be reliable in mitigating these risks.

A number of Committee members expressed interest in assisting Health Canada in this drug-related public protection initiative, and there was agreement that Ms. Wells would report this to the NAPRA Board for direction.

6. **Date of next meeting**

Saturday-Sunday, June 12-13, 2004. This will be confirmed on April 13, 2004 (submission deadline)

7 **Adjournment**

The meeting was adjourned at 4:00 pm on Monday.

Natural Health Products Directorate, Health Canada

Peter Chan A/Director, Product Review & Assessment
Deborah Yu A/Director, Promotion, Liaison & Development

Council of Pharmacy Registrars of Canada

Greg Eberhart, Registrar, Alberta College of Pharmacists
Linda Lytle, Registrar, BC College of Pharmacists
Don Rowe, Registrar, Newfoundland Pharmaceutical Association
Ronald Guse, Registrar, Manitoba Pharmaceutical Association
Bill Veniot, NB Pharmaceutical Society
Susan Wedlake, Registrar, Nova Scotia College of Pharmacists

National Association of Boards of Pharmacy (USA)

Carmen Catizone, Executive Director

BC Pharmacy Association

Marnie Mitchell, President

Canadian Pharmacists Association

Dr. Jeff Poston, Executive Director

Association of Deans of Pharmacy of Canada

Dr. Frank Abbott , Executive Director,
Dr. Robert Sinelar, Dean, Faculty of Pharmacy, UBC
Dr. Linda Hensman, Dean, Faculty of Pharmacy, MUN

Alberta Pharmacists Association

Susan Haunholter, President

Canadian Medical Association

Dr. Todd Watkins, Director, Professional Services

Ontario College of Pharmacists

Della Croteau, Deputy Registrar,
Greg Ujjiye, Pharmacy Practice Manager

Canadian Association of Chain Drug Stores

Christina Bisanz, President

Nonprescription Drug Manufacturers of Canada

Gerry Harrington

Saskatchewan Health

Dr. Kevin Wilson

McNeil Consumer Healthcare

Todd Breedon,
Peter Cummins