

A meeting of the National Drug Scheduling Advisory Committee was held Sunday & Monday, December 7-8<sup>th</sup>, at the Sheraton Hotel, Ottawa.

### Participants

Committee members:	Dr. Marilyn Caughlin (Chairman), Dr. Jeff Taylor (Vice-Chairman), Dr. Mark Armstrong, Phil Hudson, Dr. Larry Lynd, Margot Priddle, and Fred Rumpel.
Observer:	Joan Sayer
Committee resources:	Denis Belanger (Ottawa Valley Regional Drug Information Service) Micheline Ho (Therapeutic Products Directorate)
Committee secretariat & NAPRA liaison:	Barbara Wells
Guests (for portions of the meeting):	For <u>Wyeth</u> : Dr. Ross Pennie (Infectious Disease Specialist, Brant Community Healthcare System); Geoff Loucks, National Manager, Private Payer Relations; and John Andonoff, Vaccine Group Product Manager  For <u>AventisPasteur</u> : Dr. Judy Shindman, Medical Affairs; and Paul Kunert, Platform Leader, Regulatory Affairs  Don Hoffman, Senior Evaluator, Health Products & Food Branch
Regrets	Dawn Frail

## 1.0 Call to order and opening remarks

- 1.1 Introduction of new appointments: Micheline Ho, Margot Priddle  
Dr. Caughlin called the meeting to order at 9:00am, and welcomed Micheline Ho and Margot Priddle to the Committee.
- 1.2 Conflict of interest declarations  
No conflicts of interest were declared.

## 2.0 Approval of the minutes of the December 8-9<sup>th</sup> and December 17<sup>th</sup>, 2002 meetings

A few editorial amendments were made to the meeting minutes. It was moved by J. Taylor, seconded by L. Lynd, that the minutes of the meetings of December 8-9<sup>th</sup> 2002 and December 17<sup>th</sup> 2002 be approved as amended. Motion carried.

## 3.0 Approval of the agenda

Ms. Sayer asked for approval to add two items for information to the agenda and it was agreed that if time permits, these would be considered under "Other Matters." It was then moved by M. Armstrong, seconded by F. Rumpel, that the agenda be adopted as circulated and amended. Motion carried

## 4.0 For information

- 4.1 Natural Health Products (NHP) Regulations  
Ms. Ho provided an overview of the new Regulations, to be implemented January 1, 2004. She noted the development of guidance documents, and "generic" product monographs. Ms. Wells reported on a meeting she had recently attended with NHP staff members of the NHP Directorate's "Schedule II Exemption Working Group" (Schedule II being a list of substances exempted from the NHP Regulations). She also noted that the Working Group Chairman had agreed to attend this NDSAC meeting to discuss experience with the cascading scheduling process, as well as formalizing liaison and communication between NDSAC and the Working Group on matters of mutual interest. Unfortunately, the representative notified the NAPRA office on Friday that he would not be available.

4.2 Re-formulation of Kaopectate

Ms. Wells drew the Committee's attention to a Canadian Press report that the US manufacturer of Kaopectate™ had re-formulated the product by replacing attapulgite with bismuth subsalicylate to reduce lead levels. This matter had been referred to Health Canada, and it was reported that no similar action was being considered in Canada. On review of the calculated lead levels in the Canadian product, the Committee agreed that no further action was warranted.

4.3 New Model Standards of Practice for Canadian Pharmacists

Ms. Wells presented NAPRA's new detailed model Standards of Practice, noting that the intent of the document is to reflect the level of patient care expected of pharmacists. She also circulated a summary of a request from the Alberta College of Pharmacists' to their provincial government to obtain full prescribing authority for pharmacists as well as the ability to administer drugs by injection.

4.4. Federal government initiative to combat "look alike/sound alike" drug product names

Ms. Wells circulated a report on a project that is being undertaken by the Canadian government to combat the health risks caused by "look alike/sound alike" drug product names.

4.5 Correspondence re: loratadine scheduling

The Committee reviewed correspondence from an Ontario pharmacist, regarding the unscheduled status of loratadine in view of a January 2003 Canadian Adverse Reaction Newsletter article referring to convulsions caused by new-generation antihistamines. The letter had been sent to the Ontario College of Pharmacists, and they in turn, passed it on to NAPRA.

Committee members noted that in making a scheduling recommendation the balance between risks and benefits is taken into account. It was also noted that the nine reported cases referred to in the article represents a very low occurrence rate considering the volume of drug consumed. It was decided that although no further action was warranted at this time, the Committee would keep this information under advisement.

4.6 Correspondence re: nicotine replacement therapy (gum)

The Committee reviewed correspondence from an Ontario registered nurse expressing concern about the unscheduled status of nicotine replacement therapy, notably the gum form, due to a possibility of addiction to the replacement products. The letter had been sent to the Ontario College of Pharmacists, and they in turn, passed it on to NAPRA.

Committee members noted that this concern had been addressed during the scheduling deliberations, and there was evidence to show that individuals do not become addicted to nicotine replacement therapy, per se. Nonetheless, the Committee expressed interest in hearing of any personal experiences that might not support this.

4.7 Correspondence re: loperamide scheduling

The Committee reviewed correspondence from a Saskatchewan pharmacist advocating for a return of loperamide to Schedule III status to allow pharmacists to "monitor and flag sudden sales spikes, and bring trends to the attention of public health authorities". Dr. Taylor's response to the pharmacist was also reviewed and supported.

4.8 Presentation on vaccines

Mr. Don Hoffman, Biologics & Genetic Therapies Directorate, Health Canada made a presentation on Sunday morning regarding current federal approval processes for vaccines, for the information of the Committee. Vaccines for childhood immunizations were historically not put in Schedule F due to a number of factors:

- That most of the childhood immunizations are done through provincial authority in clinics or in physicians' offices, but with vaccine provided through the province. Little is sold on the open market.
- It was always felt that these were not drugs that would be abused or needed extra controls that Schedule F provides.

Ms. Wells also noted that a representative from the Immunization and Respiratory Infections Division, Population and Public Health Branch had been contacted to also present to the group on the new National Immunization Strategy, but they had not been able to provide a spokesperson at a convenient time for the Committee. For information.

4.9 Xylometazoline products for children

Ms. Wells circulated a report on her follow-up on the issue of Novartis changing the packaging of Otrivin 0.05% nasal preparations to delete references to pediatric use. At the previous meeting, the Committee had taken issue with this move, which may have propagated a circumvention of the Schedule II status of xylometazoline in nasal preparations for pediatric use. Ms. Wells agreed to research this matter further with Novartis.

5.0 **New Business**5.1 Request for Schedule I status for pneumococcal 7-valent conjugate vaccine

Wyeth representatives outlined their request for Schedule II status for PREVNAR, as presented in their submission. After an extensive question-and-answer period, the committee reviewed the scheduling factors for Schedule I. Although Factor I-2 was considered applicable to the vaccine, Committee members concurred that this Factor was not enough to warrant scheduling the vaccine in Schedule I. The Committee then proceeded to review the applicability of Schedule II scheduling factors. It was agreed that Factors II- 2, 3, 5 and 8 were applicable. It was also observed that the administration of vaccines is not restricted to physicians, and that re-scheduling this safe and effective pneumococcal 7-valent conjugate vaccine to the more restrictive Schedule I would be counter to National Advisory Committee on Immunization (NACI) recommendations. NACI recommends that the pneumococcal 7-valent conjugate vaccine be given to all children under two years of age, and Guideline #2 of Part 2 of the NACI Canadian Immunization Guide states that:

*"There should be no barriers or unnecessary prerequisites for the receipt of vaccines",*

and further, that

*"Policies and protocols should be developed and implemented so that the administration of vaccine does not depend on individual written orders or on a referral from a primary care provider".<sup>3</sup>*

**Committee members concluded that the weight of evidence (applicable factors) considered in conjunction with NACI guidelines for recommended immunizations and vaccine accessibility, warranted the retention of pneumococcal 7-valent conjugate vaccine in Schedule II.**

5.2 National Drug Schedules and Processes

The need for a formal review of the national drug scheduling model was discussed at NAPRA's Board meeting in November. The Board accepted the premise that an objective review of the national drug scheduling system was appropriate, cautioning that there would need to be solid evidence to justify any amendments in the schedules or process. This matter was referred to the Council of Pharmacy Registrars of Canada (CPRC) for further consideration, and the Registrars confirmed that given the changes in federal and provincial legislation, pharmacy practice, and the evolution of consumer empowerment since the National Drug Scheduling System was developed (well over a decade ago), a review was warranted. They asked that NDSAC initiate discussions on the relevance of the current model scheduling system, and how a review might be conducted, with recommendations to be reported back by the end of March 2004 meeting. It was also suggested that the Committee consider the use of a preliminary survey of Canadian drug scheduling stakeholders to help identify aspects of the current model to be addressed and that recommendations include survey questions and structure.

The Committee questioned the motivation for the request, wondering if concerns about the appropriateness of the current scheduling model were the result of the licensing bodies' limitations in enforcing the requisite standards of practice, rather than shortcomings of the model per se. Committee members agreed that they do support the current model, but this support is based on the assumptions that pharmacists are complying with the Standards of Practice, and that the licensing bodies are enforcing them.

It was agreed that an independent white paper was needed to evaluate the level of value added to the safe use of medications and the public's health through the conditions of sale for Schedules II and III. A vast array of stakeholders (including governments) would need to be surveyed, and data from other jurisdictions and agencies would be collated. Ms. Wells indicated that she would look into professional external resources that could be contracted to undertake this research.

The Vice-Chairman drew the Committee's attention to an article published in US Pharmacist, in June 2003, announcing the Food and Drug Administration's claim that it has legal authority to impose OTC status for some drugs. Dr. Taylor said that this was an important announcement with possible applicability to the Canadian situation, noting that the current national drug

scheduling process may not always serve the public interest in that it is only activated when a drug manufacturer requests a review. The Committee discussed the need for the federal government and/or provincial & territorial governments to assist in base funding to convene NDSAC for national drug scheduling decisions.

It was agreed that a special two-day session was warranted to focus on these important issues, plus administrative aspects identified at the previous meeting. Ms. Wells expressed concerns about proceeding without sponsorship, but agreed to explore funding possibilities so that a meeting could be held exclusive of an external scheduling request, on February 15-16, 2004.

5.3 Request for Schedule II status for Cholera vaccine (oral, inactivated) when used for prophylaxis against traveller's diarrhea & due to enterotoxigenic escherichia coli (ETEC)

AventisPasteur representatives outlined their request for Schedule II status for DUKORAL, as presented in the prepared submission. After the presentation and question and answer session, the committee reviewed the scheduling factors for Schedule I. Although Factor I-2 was considered applicable to the vaccine, Committee members concurred that this Factor was not enough to warrant scheduling the vaccine in Schedule I.

The Committee then proceeded to review the applicability of Schedule II scheduling factors. It was agreed that Factors II- 5, 8, and 9 were applicable. These factors were considered within the context that the risk of travellers' diarrhea can be readily identified through various means by the lay public (e.g., travel books, internet, personal communication and experiences), cold-chain must be preserved for proper storage, and consultation with a pharmacist is imperative to explain:

- proper dosing schedules (for both adult and pediatric patients)
- proper preparation of the vaccine for administration (stability once reconstituted, buffer for pediatric patients),
- duration of protection,
- the need for booster doses when in situations of protracted risk,
- the acquisition of natural immunity by patients as a consequence of continued exposure to ETEC, and
- the role of booster doses for patients who have previously taken the vaccine for prior travel.

**The Committee concluded that the weight of the three applicable Schedule II scheduling factors, in conjunction with the additional considerations supported scheduling in Schedule II for cholera vaccine (oral, inactivated) when used for prophylaxis against travellers' diarrhea due to enterotoxigenic escherichia coli (ETEC)..**

6.0 **Other Matters**

6.1 Renewal or election of Committee Chair and Vice-Chair

The Chairman noted that the 2002-03 term of office for the Chairman and Vice-Chairman had now expired, and called for nominations for the positions.

It was moved by Dr. Armstrong, seconded by F. Rumpel that Dr. Caughlin be nominated to serve as NDSAC Chairman for the 2003-04 term. There were no further nominations. Accordingly, Dr. Caughlin was elected by acclamation to continue as NDSAC Chairman for the 2003-04 term.

Similarly, it was moved by Dr. Caughlin, seconded by F. Rumpel that Dr. Taylor be nominated to serve as NDSAC Vice-Chairman for the 2003-04 term. There were no further nominations. Accordingly, Dr. Taylor was elected by acclamation to continue as NDSAC Vice-Chairman for the 2003-04 term.

6.2 External liaison

Ms. Sayer expressed concern that in her opinion, the Committee was not being kept informed about external matters impacting on drug scheduling, citing recent federal government initiatives such as the federal health legislation renewal as an example.

Ms. Wells noted that the examples cited were in fact, under the auspices of other NAPRA committees, and that the majority of matters under NAPRA's purview related directly or indirectly to the conditions for sale of drugs. However, having NDSAC consider matters in parallel with the Registrars, the Board, or other NAPRA Committees would not be feasible, and the Committee generally supported this. There was also support for Ms. Wells' suggestion that she could alert NDSAC members

to the availability of reports and information under NAPRA's purview that were deemed to be of particular relevance to the work of NDSAC.

**7.0 Date of next meeting**

February 15 –16<sup>th</sup>, 2004 (tentative)

**8.0 Adjournment**

The meeting was adjourned at 2:00 pm on Monday.

Scheduling/0312minutes