A meeting of the National Drug Scheduling Advisory Committee (NDSAC) was held on Sunday, April 6 and Monday, April 7 2008 at the Lord Elgin Hotel, Ottawa.

Participants

Committee members
Margot Priddle, Chair; Dawn Frail, Vice Chair; Kim Abbass; Dr. Larry Lynd; Dr. Nancy MacDonald; Dr. Ruth Wilson; Dr. Peter Zed

Observers
Don Hoffman – Therapeutic Products Directorate, Health Canada
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. Sheldon Koven

1.0 Call to order

1.1 Call to Order
Margot Priddle called the session to order at 9:00 am 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 Dec 2/07 and Jan 25/08 meetings

Draft minutes were previously circulated and approved electronically.

4.0 Business from the previous meeting

4.1 Finalization of levonorgestrel 0.75 mg and 1.5 mg scheduling request

The Chair reviewed the request made by Paladin Labs, to re-schedule levonorgestrel 0.75 mg (for emergency contraception) from the current Schedule II to Schedule III status. Similarly, the scheduling request Applicant had also requested that once deleted from federal Schedule F (prescription status), levonorgestrel 1.5 mg be assigned Schedule III status as well. Ms. Priddle noted that additional information had been received from the Applicant as well as the Interested Parties and pharmacy licensing bodies,

pursuant to the previous meeting, as had been requested by the committee. The committee reviewed the information received.

Ms. Priddle welcomed Allan Malek and colleagues to the meeting at approximately 10:00 am on Monday. Mr. Malek was in attendance to present on behalf of the Canadian Association of Chain Drug Stores, one of the organizations granted Interested Party status to the proceedings. He introduced two colleagues: Janet Cooper of the Canadian Pharmacists Association, and Cathy Lupenette, a pharmacist with Rexall Pharma Plus. The group presented their position on the scheduling of levonorgestrel 0.75 mg and 1.5 mg as requested by the Applicant, Paladin Labs. After the presentation, the group responded to questions posed by the committee members.

At 11:00 am, Lenka Janecka and Brian Stowe were welcomed to the meeting. Ms. Janecka was attending on behalf of another Interested Party, the Ontario Pharmacists Association (OPA), and was joined by Mr. Stowe (practising community pharmacist) to assist with the OPA's presentation. After the presentation, Mr. Stowe and Ms. Janecka responded to questions from the committee.

Representatives of Paladin Labs made a presentation before the committee at 12:30 pm, followed by a brief question and answer session. Attending on behalf of the Applicant were Dr. Patrice Larose, Mark Beaudet, Dr. Colleen Metge, and Farrukh Rehan.

In consideration of the various levonorgestrel products both proposed and currently on the market, the committee agreed that the scheduling of levonorgestrel should be determined in three parts:

- Conditions for sale of levonorgestrel 1.5 mg tablet, taken on a one-tablet basis (and pending the federal government's approval to remove from Schedule F);
- Conditions for sale of levonorgestrel 0.75 mg tablets, two tablets to be taken at one time (once a day); and
- Conditions for sale of levonorgestrel 0.75 mg tablets, one tablet to be taken, followed by a second in 12 hours.

The Chair led the committee through a review of the applicability of these three configurations to all scheduling factors. It was agreed that:

- Scheduling factors #II-2, III-1, III-4, III-6, and III-7 were applicable for "Levonorgestrel (when sold in concentrations of 1.5 mg per oral dosage unit, packaged and labelled for emergency contraception, in package sizes containing no more than 1.5 mg of levonorgestrel)"and that this would warrant Schedule III placement.

- Scheduling factors #II-2, III-1, III-4, III-5, III-6, and III-7 were applicable for "Levonorgestrel (when sold in concentrations of 0.75 mg per oral dosage unit to be taken as a single dose of 1.5 mg, packaged and labelled for emergency contraception, in package sizes containing no more than 1.5 mg of levonorgestrel)", and that this would warrant Schedule III placement.

- Scheduling factors #II-2, II-8, III-1, III-2, III-4, III-5, III-6, and III-7 were applicable for "Levonorgestrel when sold in concentrations of 0.75 mg per oral dosage unit (except when labelled to be taken as a single dose of 1.5 mg and in package sizes containing no more than 1.5 mg levonorgestrel), packaged and labelled for emergency contraception)" and that this warranted retention in Schedule II. It was noted that the factor #II-8 ("*Use of the drug requires reinforcement or an expansion of the directions for use, through pharmacist - patient dialogue*") was applicable in this particular configuration due to study results that showed a significant increase in patient non-compliance with twice-a-day dosing and therefore the need for intervention by a health professional.

After review and final discussion:

It was moved by D. Frail, seconded by R. Wilson that **"Levonorgestrel (when sold in concentrations of 1.5 mg per oral dosage unit, packaged and labelled for emergency contraception, in package sizes containing no more than 1.5 mg of levonorgestrel)" be granted Schedule III status, pursuant to removal from federal Schedule F.**

Motion carried

It was then moved by R. Wilson, seconded by L. Lynd that **"Levonorgestrel (when sold in concentrations of 0.75 mg per oral dosage unit to be taken as a single dose of 1.5 mg, packaged and labelled for emergency contraception, in package sizes containing no more than 1.5 mg of levonorgestrel)" be granted Schedule III status.**

Motion carried.

And finally, it was moved by D. Frail, seconded by K. Abbass that **"Levonorgestrel when sold in concentrations of 0.75 mg per oral dosage unit (except when labelled to be taken as a single dose of 1.5 mg and in package sizes containing no more than 1.5 mg levonorgestrel, packaged and labelled for emergency contraception)" be assigned to Schedule II.**

Motion carried

To be reported to NAPRA Executive Committee.

4.2 Engagement of interested stakeholders/members of the public

B. Wells presented a revised draft policy to facilitate stakeholder input into the drug scheduling deliberations. There was discussion about proposed deadlines for receipt of stakeholder information and it was agreed that any information would need to be submitted no less than seven days prior to the committee meeting, to facilitate processing, distribution, and review.

It was moved by R. Wilson, seconded by D. Frail, that **the revised draft policy be approved (as amended by the seven day deadline provision) and recommended to NAPRA for adoption.**

Motion carried.

The committee also agreed that if adopted, announcements about this new policy should highlight the fact that it now adds a second mechanism for public input to be received (i.e. along with the established Interested Party standing). There was also agreement that efforts should be made to ensure that patient and disease-specific advocacy groups are made aware of this new policy.

To be reported to NAPRA for approval.

4.3 "Parenteral nutrition" vs "total parenteral nutrition
This matter was deferred to the next scheduled meeting.

4.4 Revision of Scheduling Factors
At the request of the Chair, B. Wells led the committee through a report prepared on responses received pursuant to the public consultation on proposed revisions to the scheduling factors.

The committee reviewed each comment received, and agreed on a number of amendments to the revised factors based on these stakeholder comments and suggestions.

It was moved by N. MacDonald, seconded by L. Lynd **that the revised scheduling factors be approved as amended, and recommended to NAPRA for adoption.**

Motion carried.

To be reported to NAPRA for approval.

4.5 Guidelines for Scheduling Status Submissions
This matter was deferred to the next scheduled meeting.

5.0 New business

5.1 Scheduling change request for benzoyl peroxide (preparations of 5% or less as a single ingredient)

The committee welcomed Praveen Chawla and Dora Gelntis, representatives from Johnson & Johnson Inc. (the scheduling review **Applicant**) to the meeting at 1:00 pm. The representatives made a presentation to the committee, outlining the Johnson & Johnson request that the scheduling of "benzoyl peroxide (preparations of 5% or less as a single ingredient)" be changed from the current Schedule III to Unscheduled status. This

presentation was followed by a question and answer session with committee members.

At 2:00 pm, the Chair welcomed Guthy-Renker representatives Todd Harrison and Dr. Jon Daniels, to the meeting. Guthy-Renker had been granted **Interested Party** standing to the proceedings. The representatives presented the Guthy-Renker position, which was in support of the scheduling change of benzoyl peroxide in preparations of 5% or less as a single ingredient. The presentation was followed by a brief question and answer session with the committee.

The committee then reviewed and discussed the information previously submitted by the Applicant and the Interested Party, as well as both presentations. It was noted that the current Schedule III status for benzoyl peroxide (preparations of 5% or less as a single ingredient) had been assigned by the Canadian Drug Advisory Committee (interim body established to develop the national model schedules) in 1995.

Ms Priddle then led the committee through a review of the current applicability of this drug to all scheduling factors, and it was agreed that scheduling factors # III-1, #III-4, and #III-5 were applicable. After further discussion, it was agreed that the applicability of these factors did not warrant retention in Schedule III.

It was moved by R. Wilson, seconded by P.Zed that "**Benzoyl peroxide (preparations of 5% or less, as a single ingredient)" be granted Unscheduled status.**

Motion carried.

To be reported to NAPRA Executive Committee.

5.2 Scheduling change request for famotidine (when sold in concentrations of 20 mg or less per oral dosage unit and indicated for the treatment of heartburn, in package sizes containing more than 600 mg of famotidine).

The committee reviewed the submission provided by McNeil Consumer Healthcare **(Applicant**), requesting a change in the scheduling of famotidine (under the parameters listed above) from the current Schedule II status to Schedule III. It was noted that the current Schedule II placement was granted by the committee in December 2006. Famotidine in smaller package sizes (i.e. containing less than 600 mg of famotidine) in total is Unscheduled.

Ms Priddle led the committee through a review of the current applicability of this drug to all scheduling factors, and it was agreed that scheduling factors # III-1, #III-2, and #III-4 were applicable.

It was moved by D. Frail, seconded by K. Abbass that **"Famotidine and its salts (when sold in concentrations of 20 mg or less per oral dosage unit and indicated for the treatment of heartburn, in package sizes containing more than 600 mg of famotidine) be granted Schedule III status**.

Motion carried.

To be reported to NAPRA Executive Committee.

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

Ms. Priddle announced 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 committee members to consider nominations for these positions, to be decided before the end of June.

6.0 For information

6.1 Therapeutics Products Directorate (TPD) update

Mr. Hoffman provided a brief verbal report on recent developments at TPD of interest to the committee, including the web posting of Product Monographs regulatory amendments regarding Schedule A, and the recent *Canada Gazette* Part I publication of proposed amendment of Schedule F listing of naproxen.

6.2 Presentation regarding "Responsible Use of Nonprescription Medications"

The Chair welcomed Gerry Harrington, Nonprescription Drug Manufacturers Association of Canada (NDMAC) to the meeting at 11:00 am on Sunday. Mr. Harrington provided a presentation on recent findings from a research study conducted on the nature (extent and causes) of consumer non-compliance with non-prescription drug label directions. He noted that another phase of research is being planned, and invited the committee to submit any information gaps they had identified regarding the use of non-prescription drugs that might be probed in the next phase.

6.3 Status of new member recruitment

Ms. Wells noted that the deadline for nominations had been extended to Friday, May 2 2008.

7.0 Date of next meeting

Tentatively scheduled for Monday, June 9th, 2008. This will be confirmed after April 9th (deadline for submissions for the June meeting).

8.0 Adjournment

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