

A meeting of the National Drug Scheduling Advisory Committee (NDSAC) was held on Sunday, September 13 and Monday, September 14, 2009 at the Lord Elgin Hotel, Ottawa.

Participants

Committee members

Margot Priddle, Chair; Dr. Ruth Wilson, Vice Chair; Kim Abbass; Gail Bradley; Dr. Nancy MacDonald; Dr. Sheldon Koven; Dr. Peter Zed; Kathy McInnes

Observers

Dr. Ratna Bose – Therapeutic Products Directorate, Health Canada
Joan Sayer – Consumers Association of Canada

Staff

Lizanne Beique – NDSAC resource and pharmacist, Ottawa Valley Regional Drug Information Centre
Carole Bouchard – NAPRA Executive Director and Committee Secretary

1.0 Call to order

1.1 Call to Order

Margot Priddle called the session to order at 9:10 am and welcomed everyone to the meeting. As the committee Chair was welcoming new members and participants she invited members to introduce themselves and say few words about their background.

1.2 Conflict of interest declarations

Ms. Priddle called for conflict of interest declarations. Dr. MacDonald indicated that she had worked for one of the companies that is presenting a submission. However, her employment with the company ended upon her retirement more than 5 years ago, and she has never had responsibilities related to the subject product. The committee members did not feel that this represented a conflict of interest. No other members had anything to declare. 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 June 8-9 and July 21, 2008 meetings

It was noted that the agenda should have referred to the minutes of 2008 meetings and not 2009. This was corrected and minutes approved.

Members asked for a status report regarding the item 4.2 of the June 8-9 meeting minutes. This item pertained to the motion the committee made to suggest the implementation of a new policy whereby scheduling requests would not be considered unless a Notice of Compliance (NOC) had been granted for the product.

The Chair provided an update on what happened subsequent to this motion regarding the assessment of its implications. She reminded everyone that further assessment of the impact of the motion the committee members proposed that the final text of the Product Monograph available at the time of the NOC, be included as part of the information package considered during the course of making scheduling recommendations. This would allow for initiation of the scheduling process prior to the release of the NOC.

A discussion followed where the members questioned again if the review should only start after the NOC is granted. Several comments and ideas were formulated on the advantages and disadvantages of starting the review of a submission before the NOC is granted. A detailed explanation of both processes at the NAPRA/NDSAC and Health Canada levels along with their interrelations, were provided and discussed.

Having heard all the facts the members reconfirmed that they would be satisfied with maintaining the process as is with the caveat that the committee will not forward its interim recommendation to the Executive Committee (signalling the start of the 30-day approval period) until the text of the final Product Monograph has been received and reviewed for any significant changes. This approach would have the same advantage as the other option (which would have added a step to have the approved scheduling recommendation come into effect pending review of the approved Product Monograph) and not cause undue delay to the process. As well, that option would not require amendments to the bylaws to implement as it is the committee's prerogative to collect information deemed to be necessary to make a scheduling recommendation, and the committee is in agreement that approved Product Monograph is an important document for scheduling.

The committee also reiterated their agreement to allow the NAPRA office to perform on their behalf a comparison between the documents available at the time of the NOC and those reviewed by NDSAC to ensure that there are no significant changes.

4.0 Business from previous meetings

4.1 Guidelines for Scheduling Status Submissions

The Chair mentioned the work that has been done over the past few years on the development of guidelines to assist manufacturers in the preparation of their submissions. She asked members who were involved to forward to the secretariat the latest electronic version of the draft document. This will help in preparing a status on this document and deciding on the next steps.

4.2 Clarification of "parenteral nutrition" vs "total parenteral nutrition" This matter was deferred to a future meeting.

4.3 Reference chart of scheduling structure in similar jurisdictions e.g. US, UK, AU, NZ, EU This matter was deferred to a future meeting.

5.0 New business

5.1 Scheduling change request for methocarbamol

The committee was informed that there were no Interested Parties other than the sponsor involved in this request. Furthermore, no comments were received from the public through the alternate method of participation recently implemented.

The committee welcomed Murray Brown and Narinder S. Grewal, representatives from Wyeth Consumer Healthcare Inc. to the meeting at 11:00 am. The representatives made a presentation to the committee, outlining the Wyeth Consumer Healthcare Inc. request that the scheduling of "methocarbamol" be changed from the current Schedule III to Unscheduled status. This presentation was followed by a questions and answers session with committee members.

The committee reviewed and discussed the information previously submitted by the Applicant and their presentation. The committee members discussed issues related to the safety and efficacy of the product. In consideration of the committee's mandate, the product's adverse effects profile, including its anticholinergic effects, were further discussed.

The Chair 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 # I- 2, # III-3, and # III-5 were applicable. After further discussion, it was agreed that the applicability of these factors warranted retention in Schedule III.

It was moved by R. Wilson, seconded by S. Koven that **"Methocarbamol (except for parenteral use) be retained in Schedule III.**

Motion carried.

To be reported to NAPRA Executive Committee.

5.2 Scheduling change request for Diphenhydramine

The committee was informed that there were no Interested Parties other than the sponsor involved in this request. Furthermore, no comments were received from the public through the alternate method of participation recently implemented.

Ms Priddle welcomed Jill Grande and Todd Breedon, representatives from McNeil Consumer Healthcare at 15:00. Ms. Grande made a presentation to the committee regarding their request to have "Diphenhydramine and its salts and preparations (for topical use in concentrations of 2% or less) when sold in containers of 300 mg or less" be moved from Schedule III to Unscheduled status. This was followed by a period of questions and answers.

The committee reviewed and discussed the submission previously provided by McNeil Consumer Healthcare and their presentation.

The Chair led the committee through a review of the current applicability of this drug to all scheduling factors, and it was agreed that scheduling factor # III-5 was applicable. After further discussion, it was agreed that the applicability of this factor did not warrant the retention of this drug in the concentrations and containers involved in the request, in Schedule III. However, the committee members suggested that the company be asked to consider adopting the wording of the US labeling. For instance, they should use do not apply on "large" areas of the skin instead of on "extensive" areas. A mention of not using the product on blistered areas of the skin as well as not using the product at the same time as other diphenhydramine products, including oral formulations would be important to add on the labelling. It was recommended that these suggestions be also shared with Health Canada.

It was moved by S. Koven, seconded by P. Zed that **"Diphenhydramine and its salts and preparations (for topical use in concentrations of 2% or less) when sold in containers of 300 mg or less of diphenhydramine hydrochloride"** be granted Unscheduled status.

Motion carried.

To be reported to NAPRA Executive Committee.

5.3 Scheduling status for Levonorgestrel 0.75 mg/tablet

C.Bouchard indicated that it was brought to NAPRA's attention that a new product containing levonorgestrel 0.75 mg/tablet packaged in a two-tablet format for emergency contraception, received a notice of compliance from Health Canada and did not include the same labelling information on the outside of the package as the committee members reviewed in 2008 at the time of the formulation of their initial recommendations. Members were asked to provide guidance regarding the placement of products that may not have the information on the outside of the package intended for self selection placement as they requested at the time of the review.

It was moved by N. MacDonald and seconded by R. Wilson that NAPRA *clarifies* that all "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 Schedule II status unless the outside of the package is *appropriately* labelled as per the committee members' recommendations for *self-selection* in order to fall under Schedule III status. In addition to the information Health Canada requires on the outside of the package, the Committee identified the following information to be placed on the outside of the package and visible to the consumers.

- Side effects: the product may cause temporary side effects in some users. Nausea, headache and low abdominal pain are the most common. Fatigue, dizziness, breast tenderness, vomiting and

diarrhea may also occur. If symptoms are severe or persist more than two days, contact your health care provider. See your doctor right away if you have a severe stomach pain, since this can be a warning sign of a tubal pregnancy – a serious medical problem. Your next menstrual period should come on time, but may be a few days early or late. If it is more than a week late, a pregnancy test is recommended. Spotting may occur a few days after treatment. Over dosage can increase side effects and may cause menstrual cycle disturbances.

- Studies indicate that the product acts as an emergency contraceptive by preventing the release of an egg from the ovary, or by preventing sperm and egg from uniting. In addition, the product may prevent the fertilized egg from attaching to the wall of the uterus. The product cannot terminate a pregnancy once a fertilized egg has become attached to the wall of the uterus. Therefore, pregnant women should not use this product.
- The product is most effective if the treatment is started in the first 24 hours after unprotected sex. Treatment should be started within 72 hours. Do not exceed the recommended dose; effectiveness will not increase.
- After a single act of intercourse the pregnancy rate was less than 1% for women who started treatment within 72 hours of intercourse. With no contraception, the expected pregnancy rate is 8% after a single act of intercourse.

Motion carried.

To be reported to NAPRA Executive Committee

5.4 Election of Chair, Vice-Chair for 2009-10

Ms. Priddle announced that her second term as a committee member and also Chair would be ending this month. Although there is a possibility that she stays for another short term to allow for the recruitment of another member and the transfer of corporate knowledge, a replacement for the Chair would be needed. C. Bouchard facilitated the process and asked for nominations from members for the Chair. It was proposed by members that Ms. Priddle and Dr. Ruth Wilson remain Chair and Vice-Chair until spring 2010 when Dr. Ruth Wilson will then move to the Chair position and a new member would be appointed Vice-Chair. It was strongly suggested that members in their first terms consider running for the Vice Chair position.

C. Bouchard will report to the Executive Committee the results of the election and seek reappointment of Ms. Priddle for one year term. In addition, Dr. Nancy MacDonald confirmed her interest to continue for a second term of three years. Her reappointment will be proposed to the Executive Committee.

6.0 For information

- 6.1 NAPRA Natural Health Products Policy / update
C. Bouchard informed the committee members of the Board decision to re-examine the policy for Natural Health Products issued in 2006. In the meantime the Board agreed that the Natural Health Products currently listed in the National Drug Schedules be maintained in the drug schedules until the Board of Directors is apprised of results of the re-examination and have made a decision.
- 6.2 Pancreatic Enzymes and correspondence received
C. Bouchard and M. Priddle informed the committee members of correspondence received by the Chair from a few medical societies regarding the scheduling of pancreatic enzymes when used for the treatment of established pancreatic insufficiency. These groups conveyed to the Chair their support for the maintenance of Schedule I status and their hope that it be not removed from the National Drug Schedules.
- 6.3 Additions made to Schedule F (2008/2009)
The members were informed that a list was prepared and asked if this type of information was useful. It was agreed that such a list is not necessary. However, the members indicated that they would like being informed of products that might be in the process of switching from a prescription to non-prescription status. Members were informed of the Health Canada proposal to switch fluconazole 150 mg single oral dose from a prescription to a non-prescription status, initiated earlier on this year.
- 6.4 Therapeutics Products Directorate (TPD) update
Dr. Bose informed the committee members of the US situation regarding acetaminophen and liver related injury. She shared highlights of what would be possible upcoming changes affecting acetaminophen containing products in the US. In Canada a proposal to change labelling standards for acetaminophen products was published last February by Health Canada. Comments received were reviewed and the document is now being finalized. A draft copy of the proposal can be found on the Health Canada website.

This issue generated discussions and members recommended that the Board be apprised of this matter and consider asking NDSAC to initiate a possible review of acetaminophen products in the public interest.

7.0 Date of next meeting

Tentatively scheduled for December 6 and 7, 2009. Tentative meeting dates were also scheduled for 2010 as follow: March 7-8, June 6-7, September 12-13 and December 5-6. The Chair and C. Bouchard reviewed some administrative matters with the members. It was suggested that more detailed procedures regarding the disposal of confidential information be made available to the members.

8.0 Adjournment

The meeting was adjourned at approximately noon on Monday.