

Minutes of the National Drug Scheduling Advisory Committee December 2, 2007

A meeting of the National Drug Scheduling Advisory Committee (NDSAC) was held on Sunday, December 2, 2007, at the Lord Elgin Hotel, Ottawa.

Participants

Committee members

Margot Priddle, Chair; Dawn Frail, Vice Chair; Kim Abbass; Dr. Sheldon Koven; 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

Karen Wolfe – Executive Director, NAPRA
Barbara Wells – Consultant, NDSAC Secretariat

Guests

Todd Breedon, Jeff Harris – McNeil Consumer Health Care (9:30 – 10:30 am)
Shawn O'Reilly, Dr. Paul Saunders - Canadian Association of Naturopathic Doctors (1-2:00 pm)

1.0 Call to order

1.1 Call to Order

Margot Priddle called the session to order at 8:30 am and welcomed everyone to the meeting.

1.2 Introduction of new members

The Chair welcomed the newest committee members, Kim Abbass and Peter Zed, to the meeting, and introductions were made.

1.3 Conflict of interest declarations

Ms. Priddle called for conflict of interest declarations. Dr. MacDonald indicated that she was a former employee of McNeil Consumer Health Care, the day's scheduling request applicant. Mr. Hoffman indicated that he had been involved in Health Canada's evaluation of ranitidine for deletion from Schedule F, a number of years ago. It was agreed that the involvements disclosed did not present conflicts of interest.

Conflict of interest forms concerning the matters to be considered at the meeting were completed and submitted.

2.0 Approval of the agenda

The agenda was approved as circulated

3.0 Approval of the minutes of the September 16-17, 2007 meeting

Draft minutes were previously circulated, revised, and approved electronically, and subsequently posted on the NAPRA website.

4.0 Business from previous meeting

4.1 Engagement of interested stakeholders/members of the public

Karen Wolfe outlined a draft policy previously circulated, regarding mechanisms for facilitating input to the committee from interested stakeholders and other members of the public.

Committee members offered a number of suggested amendments.

With respect to the Drug Scheduling External Liaison Group (DSELG) list, Dr. Wilson suggested that NAPRA review submissions archived from the past 1-2 years, to obtain potential DSELG additions.

ACTION: NAPRA to revise draft policy in accordance with feedback and re-circulate.

4.2 "Parenteral nutrition" vs "total parenteral nutrition" vs "Parenteral Therapy"

The Chair welcomed Shawn O'Reilly and Dr. Paul Saunders, representatives of the Canadian Association of Naturopathic Doctors (CAND) to the meeting at 1:00 pm.

The guests made a presentation and outlined the rationale for CAND's request to meet with NDSAC, to:

- Initiate a formal relationship between the two groups,
- Provide information on the education, training and practice of naturopathic doctors, and specifically to
- Seek clarification of the intent of National Drug Schedule (NDS) entries that are specified "for parenteral use" or "for total parenteral use".

Naturopathic doctors (ND) commonly use injectable vitamins, minerals and other nutrients in their practices, and are often not able to obtain supplies due to their Schedule I status (requiring a prescription from a "practitioner" which does not always include NDs due to provincial regulations). CAND was seeking to understand if it was the intent of the NDS to restrict use of these substances to medical practitioners only.

There was considerable discussion about this matter, and it was agreed that more background research into the issue was needed. The Committee thanked the guests for their presentation and attendance.

ACTION:

1. CAND agreed to compile a list of applicable NDS entries for submission to NAPRA
2. NAPRA to consult original NDS document (1995) for possible definitions or indications of intent, as well as federal legislation.

4.3 Revision of Scheduling Factors

Ms. Wolfe reported that the external consultation on the proposed revised scheduling factors was still underway, with the deadline for responses being December 10. She said that while no feedback had been received to-date, a number of organizations have indicated their intent to submit responses.

4.4 Guidelines for Scheduling Status Submissions

The committee reviewed a revised guideline document originally developed by Larry Lynd, and edited by Barbara Wells.

There was significant discussion about the guideline contents, specifically the nature of the benefit/risk requirements proposed in the document.

There was agreement that:

- the revised version of the scheduling factors should be included (pending the results of the current consultation)
- new information about pre-meeting notifications and consultations (e.g. for Interested Party applications, and other stakeholders input) should be included,
- the fact that the advice given in the document is guidance only and not mandatory should be highlighted, and that
- guidance on product labelling and consumer studies should be augmented.

ACTION:

1. **Committee members are to send comments to Barbara Wells, to incorporate into next draft (for approval at March 2008 meeting).**
2. **Karen Wolfe to determine if external consultation is required prior to finalization by NAPRA Council.**

5.0 New business

5.1 Scheduling change request for ranitidine 150 mg

The Chair welcomed the McNeil Consumer Healthcare representatives to the meeting, at approximately 9:30 am. Mr. Breedon and Mr. Harris made a presentation summarizing the request to re-schedule larger package sizes of ranitidine 150 mg from the current Schedule II to III.

During the presentation, reference was made to a possible re-scheduling of famotidine 20 mg to Schedule III. It was brought to the McNeil representatives' attention that it had been the understanding of NAPRA and the committee that this scheduling request concerned ranitidine only.

After completion of the presentation and a short question-and-answer period, it was determined that further information was needed from the applicant, namely:

- Labelling standards and/or templates
- Data on experience with ranitidine and famotidine as unscheduled drugs
- Periodic safety update report (PSUR) data in the interim since February 2007 switch in Canada – for ranitidine and famotidine

- Actual consumer survey conducted by McNeil, methodology and complete summary of results.
- Amplification of demographic data, by product
- August 2007 NDMAC “Public Awareness of Cautionary Statements” study – study report (not raw data), to include methodology, questions and a summary of responses

It was moved by L. Lynd, seconded by S. Koven that further consideration of the re-scheduling of ranitidine 150 mg, as requested by McNeil Consumer Health Care be deferred until the next meeting, March 2008, when the additional information is obtained. Motion carried.

The Committee also discussed next steps with respect to consideration of famotidine. It was pointed out that the requisite public notification had not been done for this molecule and to proceed without this notice and public information would be a breach of process.

It was moved by D. Frail, seconded by R. Wilson that consideration of the request to re-schedule famotidine 20 mg would be deferred to March 2008, pending application of the usual administrative process. Motion carried.

The Committee also requested that the Ottawa Valley Regional Drug Information Service (OVRDIS) conduct a Med-line search for data on the use of non-prescription H2 antagonists (world-wide).

ACTION:

1. **B.Wells to advise McNeil Consumer Health Care of the decisions to defer, as well as the outstanding information requests.**
2. **B. Wells to follow-up with OVRDIS for the literature search.**

6.0 For information

6.1 Additions made to Schedule F

Committee reviewed the list of implemented and proposed amendments to Schedule F, and noted that one (Project #1535 re: Calcium salts when sold for the treatment of hyperphosphatemia) would need to be reviewed to assess implications for the NDS calcium entries.

ACTION: K. Wolfe to develop proposed changes for NDS terminology, for review at next meeting

6.2 TPD update

At the Chairman’s invitation, Don Hoffman provided a brief verbal update on Therapeutic Products Directorate activities of relevance to the Committee.

7.0 Date of next meeting

March 9-10, 2008. This is expected to be a two-day meeting.

8.0 Adjournment

The meeting was adjourned at 2:20 pm.