

National Drug Scheduling Advisory Committee Teleconference Meeting Minutes January 25, 2008

A meeting of the National Drug Scheduling Advisory Committee (NDSAC) was held by teleconference on Friday, January 25, 2008 starting at 1:30 pm EST. The purpose of the meeting was to continue discussion of the request to re-schedule "Ranitidine and its salts, when sold in concentrations of 150 mg or less per oral dosage unit and indicated for the treatment of heartburn, in package sizes containing more than 4500 mg of ranitidine" from Schedule II to Schedule III.

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 –NDSAC Secretariat

1.0 Call to order

1.1 Call to Order

Margot Priddle called the session to order at 1:30 pm and welcomed everyone to the meeting.

1.2 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 scheduling request applicant. It was agreed that the involvement disclosed did not present conflicts of interest.

2.0 Approval of the agenda

The agenda was approved as circulated

3.0 Ranitidine and its salts

Ms Priddle reviewed the information requested by the committee at the previous meeting and that which was provided. At the December 2007 meeting, the scheduling applicant (McNeil Consumer Healthcare) had been asked to obtain additional information in a number of areas, for the committee's consideration. In addition, the committee reviewed further information obtained by the Ottawa Valley Regional Drug Information Service, as requested. The Chair asked if Committee members now had sufficient information to continue their deliberations, and all agreed.

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After reviewing all the scheduling factors, the Committee agreed that factors #III-1, 2, and 4 only, applied.

It was moved by S. Koven, seconded by L. Lynd, that "***ranitidine and its salts, when sold in concentrations of 150 mg or less per oral dosage unit and indicated for the treatment of heartburn, in package sizes containing more than 4500 mg of ranitidine***" be granted Schedule III status.

Motion carried.

4.0 Date of next meeting

March 9-10, 2008. The meeting agenda is expected to require a full two days.

5.0 Adjournment

The meeting was adjourned at 2:20 pm.