A meeting of the National Drug Scheduling Advisory Committee (NDSAC) was held by teleconference call on Monday, July 21, 2008 starting at 10:30 am EST. The purpose of the meeting was two-fold: to consider the additional documents that had been submitted by Bayer Canada subsequent to the previous meeting at the request of the committee, and to work towards finalizing (a) recommendation(s) for the scheduling of naproxen sodium 220 mg per oral dosage unit.

Participants

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

Observers
Don Hoffman – Therapeutic Products Directorate, Health Canada
Joan Sayer – Consumers Association of Canada

Staff
Barbara Wells –Secretariat

Regrets
Dr. Nancy MacDonald, Norma Lynn Pearson

1.0 Call to order

Margot Priddle called the meeting to order at 10:35 am EST and thanked everyone for taking the time to review the circulated materials and to participate in the call.

It was noted that since Dr. MacDonald had not participated in the June 8-9th meeting where the issue of naproxen sodium scheduling had been introduced and discussed, she would not be participating in this follow-up session.

2.0 Naproxen Sodium

At the request of the Chair, Ms. Wells outlined the events prior to today's session:

- at the previous meeting, the committee had requested additional documents which had been subsequently provided by Bayer, namely:
  - an abstract regarding interactions between low dose ASA and naproxen, and
  - a Cochrane Collaboration review comparing acetaminophen with naproxen.

  Also, a study by Temple et al was referred to, and although it was accessed on-line during the meeting, there had not been sufficient time for committee members to review it. This information was also requested and received from Bayer. All documents received were pre-circulated to the committee.

- Bayer had requested permission to participate in this teleconference meeting. After consultation with the Chair and Vice-Chair the request was declined, however the Applicant was advised that they could provide further input in writing, if desired. Commentary was provided by Bayer (July 11, 2008

correspondence) in conjunction with the requested materials, and this document was also circulated to committee members.

Ms. Priddle then led the committee through a review of the new documents. It was agreed that nothing in the material affected the committee's application of the scheduling factors during the previous meeting, and further, that the material did not raise any new issues or questions.

There was considerable discussion however, about the fact that a Notice of Compliance (NOC) had not yet been issued for this product and accordingly, there was the potential that the Health Canada consultation process (i.e. through Canada Gazette Part I) could potentially result in amendments to information and material considered in the scheduling process such as proposed labelling elements (including the Product Monograph) and other aspects that had been previously presented to the committee. Committee members were not comfortable making a final decision without an opportunity to consider aspects of the approved Product Monograph (PM), which would be available on issuance of the NOC.

It was agreed that this information would be conveyed to the Applicant, and a scheduling recommendation for naproxen sodium 220 mg would be deferred pending review of the approved Product Monograph. Any differences between the approved PM and the information previously provided to the committee would be identified and if warranted, considered by the committee via a second teleconference meeting to be arranged if necessary.

3.0 Date of next meeting

The next face-to-face meeting of the committee was tentatively scheduled for December 7-8, 2008. Deadline for receipt of submissions is October 8.

4.0 Adjournment

The meeting was adjourned at approximately 11:00 am.