

**Minutes of the National Drug Scheduling Advisory Committee Meeting
June 10-11, 2007**

A meeting of the National Drug Scheduling Advisory Committee (NDSAC) was held on Sunday June 10, 2007 and Monday June 11, 2007 at the Lord Elgin Hotel at 100 Elgin Street, Ottawa.

Participants:

NDSAC Members: Margot Priddle (Chair), Dawn Frail (Vice-Chair), Dr. Anita Carrie, Phil Hudson, Dr. Sheldon Koven, Dr. Larry Lynd, Dr. Nancy MacDonald, Dr. Ruth Wilson

Observers: Don Hoffman, Joan Sayer

Staff: Karen Wolfe (Executive Director, NAPRA)
Norma Lynn Pearson, Ottawa Valley Regional Drug Information Service

Guests: **Novartis Canada Inc.:** Don Beatty (Director Scientific & Regulatory Affairs), Katharine Manson (Scientific & Regulatory consultant, CanTox)

Altana Pharma: Alan Davis (VP, Scientific Affairs, Altana Pharma), Lauren Nicol (Regulatory Affairs Associate, Altana Pharma), Kathy Palma (VP Research & Development, Piedmont Pharm), Archana Puri (Medical Information Associate, Altana Pharma)

1.0 Call to Order, Opening Remarks and Welcome of New Members

Chair M. Priddle called the meeting to order at 9:05 am and those participating introduced themselves. M. Priddle welcomed Don Hoffman, Assessment Officer, Non-prescription Drug Evaluation Division, Bureau of Gastroenterology, Infection and Viral Diseases, Therapeutic Products Directorate. Mr. Hoffman replaces Micheline Ho, who recently retired from Health Canada.

1.1 Conflict of Interest Declarations

The Chair called for Committee members to declare any real or perceived conflicts of interest. D. Hoffman indicated he was the lead assessment officer in both sponsor submissions being presented to NDSAC and he may be unable to share information regarding confidential files for both products. No other conflicts were declared.

2.0 Approval of the Agenda

M. Priddle proposed amending the agenda to discuss item 6.0 before items 4.0 and 5.0.

On a motion by R. Wilson, the Agenda was approved as amended.

3.0 Approval of the Minutes of the March 2007 NDSAC Meeting

It was noted that the Minutes from the March 2007 NDSAC meeting had been approved by electronic voting of the meeting attendees, and had been subsequently posted on the National Association of Pharmacy Regulatory Authorities (NAPRA) website.

4.0 Preparation for Drug Scheduling Review Discussion

M. Priddle and K. Wolfe informed the Committee of Interested Party (IP) status granted to Bayer Inc. in the review of 1% topical diclofenac and of the subsequent exchange of interrogatories between the IP, the sponsor, and NAPRA. Legal opinion was sought during this time to ensure compliance with the Rules of Procedure as well as to provide NDSAC options on how to proceed in this matter. It was recommended that NAPRA legal counsel prepare and present the Committee with an overview of the Rules of Procedure, particularly as they apply to IP Status, for the next regularly scheduled meeting of NDSAC.

5.0 Manitoba Pharmaceutical Association Request: Scheduling Review of Parenteral Bupivacaine

The Manitoba Pharmaceutical Association is requesting NDSAC review the scheduling status of Bupivacaine and its salts (for parenteral use). This medicinal ingredient is currently Schedule II. A preliminary review of parenteral local anaesthetics reveals that all are Schedule II products. According to the Therapeutics Products Directorate Drug Product Database, these are classified as *ethical* products meaning:

A drug that in accordance with federal legislation does not require a prescription but that is generally prescribed by a medical practitioner e.g. nitroglycerin.

This agenda item will be reviewed in depth at the next regularly scheduled NDSAC meeting to allow time for preparation of background materials for review.

6.0 Definition of “parenteral nutrition” versus “total parenteral nutrition” in the National Drug Schedules

The terms “parenteral” and “TPN” are used interchangeably, thus leading to a lack of clarity in interpretation of the National Drug Schedules. This agenda item will be reviewed in depth at the next regularly scheduled NDSAC meeting to allow time for preparation of background materials for review.

7.0 Request for Initial Scheduling of 1% topical diclofenac to Unscheduled

Representatives from CanTox (on behalf of Novartis) made a presentation to the Committee to support their initial scheduling request to have 1% topical diclofenac be Unscheduled. This request was based upon their twenty years of historical safe use in OTC environments around the world.

The Committee determined that the following scheduling factors were applicable to this medicinal ingredient: Schedule I – Factor #2; and Schedule III – Factors #1, #7, and #9. These factors were considered sufficient for the Committee to schedule the medicinal ingredient in Schedule III. During their deliberations, the Committee was challenged by the lack of clarity in the exact wording that would be used in the regulatory amendment to remove this medicinal ingredient from Schedule F (since the Canada Gazette I proposal was not available at the time of the meeting). Other considerations included the delivery vehicle, and the potential for diclofenac to be compounded in the absence of commercially available products.

It was moved by R. Wilson that “diclofenac diethylamine in preparations for topical use on the skin in concentrations of not more than the equivalent of 1% diclofenac” be Schedule III.

The motion was carried.

8.0 Revised Scheduling Factors

K. Wolfe reported on comments received in the early phases of the consultation on revised scheduling factors, specifically the lack of a guide to assist in consultation and the rationale for the changes. Consultation has been suspended for the time being to consult with NDSAC regarding the historical development of these revised factors.

It was noted that the scheduling factors review had been underway since 2002, when it was decided to edit the existing scheduling factors with a view to clarifying their intent. The goals were to develop single criteria statements relevant to today’s practice environment, and to ensure that streamlined decision points for the Committee were clear. K. Wolfe to re-initiate consultation process.

9.0 Content of Submissions – consideration of CIOMS Criteria

Dr. L. Lynd explained the rationale for Draft 2 of the Guidelines for Scheduling Status Submissions. Plans are to condense the document down to a checklist that is more practical, user-friendly, and applicable to the work of NDSAC. Dr. N. MacDonald collaborate with Dr. Lind in this regard.

Dr. Lynd agreed to collate responses if received by June 25. This draft will be sent to NAPRA for administrative review with hopes of having a final draft available by the September meeting.

10.0 Request for Initial Scheduling of 50% Isopropyl myristate for use in the treatment of head lice to Schedule III

Representatives from Altana Pharma made a presentation to the Committee to support their initial scheduling request to have 50% isopropyl myristate be in Schedule III.

The Committee agreed that the following scheduling factors were applicable to this medicinal ingredient: Schedule III – Factors #1, #4, #5, and #7. These factors were considered sufficient for the Committee to schedule the medicinal ingredient in Schedule III.

It was moved by R. Wilson that “50% Isopropyl myristate for use in the treatment of head lice” be Schedule III.

The motion was carried.

11.0 Update from TPD – D. Hoffman

- Dr. Supriya Sharma is acting Director General for TPD.
- Etienne Ouimette is Associate Director General for TPD (as of March 12 for a 4 month term).
- Product Monograph Part III is now being posted on the Health Canada website as part of the Summary Basis of Decision initiative.
- The TPD and the Natural Health Products Directorate (NHPD) are continuing to develop product monographs for drugs and NHPs to assist the evaluation of the safety and efficacy of medicinal ingredients commonly used in these products (for licensing purposes) and to inform consumers. Most recent monographs are for medicated skin care products and diaper rash products.
- Regarding the diagram depicted on the carton in the submission reviewing ranitidine 150mg – follow-up with TPD at Health Canada indicated the diagram could reasonably be construed as heartburn, not GERD.
- Regarding the labeling of diphenhydramine (when used as a sleep aid) – confirmed that the labeling standard addressed the elderly.

12.0 Date of Next Meeting

The next NDSAC meeting is scheduled for September 16-17, 2007, subject to the receipt of a submission by the July 18th deadline.

13.0 Closing Comments and Adjournment

M. Priddle thanked the participants for their hard work, and expressed sincere appreciation for the exceptional contributions of P. Hudson, who was attending his last NDSAC meeting. M. Priddle also thanked D. Hoffman from TPD for his contributions during his first meeting.

The meeting was adjourned at 12:50 pm.

Recorded by: K. Wolfe