

A meeting of the National Drug Scheduling Advisory Committee (NDSAC) was held on Monday, March 4, 2013 at the Lord Elgin Hotel, Ottawa.

Present:

NDSAC members:

Kathy McInnes (Chair); Kim Abbass (Vice Chair); Dr. Tom Bailey; Dr. Murray Brown; Drena Dunford; Dr. Carlo Marra; Dr. Peter Zed

Observers:

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

NAPRA Staff:

Carole Bouchard – Executive Director
Sarah Marshall – Manager, Professional and Regulatory Affairs, Committee Secretary

Regrets:

Gail Bradley

1.0 Call to order

1.1 Call to Order

K. McInnes called the meeting to order at 9:04 a.m. on March 4, 2013 and welcomed everyone, specifically new members Dr. Murray Brown and Ms. Drena Dunford.

1.2 Conflict of interest declarations

K. McInnes called for conflict of interest declarations. None of the members had any conflicts of interest to declare.

2.0 Approval of the agenda

J. Sayer requested an addition to the agenda under section 5 to allow her to provide a brief update to members on certain matters. This was accepted by chair K. McInnes. A motion to approve the agenda as amended was put forward by Dr. Bailey and approved by consensus.

3.0 Approval of the minutes from the December 2-3, 2012 meeting

A motion to approve the minutes as posted on the NAPRA website was put forward by Dr. Marra and approved by consensus. K. McInnes reminded members of the need to properly destroy all electronic and hard copies of confidential meeting materials.

4.0 New Business

4.1 Request for Unscheduled status for bisacodyl 5mg tablets and 10mg suppositories.

The committee reviewed and considered the application for drug scheduling, as well as additional scientific literature prepared by an external drug information service for the NDSAC secretariat. No requests for interested party status were received for this review. One submission that did not support the scheduling request was received via the alternate method of participation.

At 10:30am, K. McInnes introduced and welcomed representatives from Boehringer Ingelheim: Dr. Nico Landes, Global Medical Advisor; Dr. Jeff Kawamoto, Associate Director, Drug Regulatory Affairs and Ms. Marcia Sam, Associate, Drug Regulatory Affairs. Boehringer Ingelheim representatives gave a short presentation to the committee regarding the request for Unscheduled status for bisacodyl 5mg tablets and 10mg suppositories, which was followed by a question and answer period.

The committee then discussed the information previously provided to them for review and consideration, as well as the information received during the company's presentation and the subsequent question and answer period.

Members noted that the information presented did not account for the product's use as a bowel preparation, which is an approved indication for bisacodyl. They felt that a pharmacist should be available for consultation on how to use bisacodyl as part of a bowel preparation, which can be complicated for patients to understand and is not addressed in the product labelling.

Members noted that the outer labelling of the product was limited and missing information. They felt that although the inner package insert contained detailed information for the consumer, a pharmacist should be available to provide this missing or limited information not available to the consumer prior to purchase. Members cited many examples of missing or limited information on the outer labelling, including the following:

- Contraindications: the outer labelling does not warn consumers to avoid this product in: pregnancy, allergy, nor many of the other contraindications listed in the product monograph.
- Interactions: the outer labelling does not warn consumers to avoid using bisacodyl tablets if they are on proton pump inhibitors (PPIs) or H₂ blockers, it only warns them not to take with antacids or within 2 hours of another medication. The outer labelling also does not warn of the possible interaction with diuretics, corticosteroids or cardiac glycosides.

The formulation of the product was also discussed by NDSAC members. They noted that the formulation of the product contains tartrazine, a known allergen. The committee is of the view that unscheduled status would expose more individuals to tartrazine and could potentially increase the risk of adverse reactions. The outer label does list tartrazine as a non-medicinal ingredient. However, since consumers may be allergic to tartrazine without knowing it, it was felt that having access to a pharmacist would provide an opportunity for the consumer to learn more about the possible adverse effects of tartrazine.

Members discussed how the availability of large pack sizes might affect the applicability of the scheduling factors pertaining to chronic use. Members felt that chronic use of bisacodyl could delay recognition or mask the symptoms of serious diseases such as bowel obstruction or cancer. Although not indicated for chronic use, Periodic Safety Update Reports and Canada Vigilance reports showed that bisacodyl is being used chronically for various reasons and thus individuals may be subject to the risk of delayed recognition and treatment of these conditions. This fact, coupled with the fact that stimulant laxatives, including bisacodyl, were not considered first line treatments for the

relief of occasional constipation in any of the information presented or consulted during this review, led members to suggest that the availability of a pharmacist to assist the consumer with product selection could promote safe and effective use of the drug.

Members also discussed the fact that the information presented and consulted demonstrated that the potential for misuse and abuse of stimulant laxatives, including bisacodyl, could be significant, particularly in teenagers. It was felt that a pharmacist should be available to provide advice and assistance to patients who may be more at risk of abuse and misuse of laxatives.

K. McInnes led the group in a review of the applicability of the National Drug Scheduling Factors. It was agreed that the following scheduling factors were applicable to bisacodyl 5mg tablets and 10mg suppositories:

- #II-5, #III-1, #III-4 and #III-5.

Members agreed that considering the weight of each applicable factor, all strengths and forms of bisacodyl should be retained in Schedule III.

MOTION: It was moved by Dr. Zed, seconded by Dr. Bailey: **to recommend leaving bisacodyl and its salts in all strengths and forms as a schedule III drug.**

Motion carried. All members agreed to the above noted motion.

This recommendation will be reported to the NAPRA Executive Committee.

5.0 Updates

5.1 Therapeutic Products Directorate

Dr. Bose shared information on the Health Products and Food Branch's 2012-2015 Strategic Plan, and how the priority 'The Regulatory Roadmap' may impact the nonprescription drug authorization process. Information on the 'Regulatory Initiative: Prescription Status of Drugs (Repeal of Schedule F)' was also shared.

Dr. Bose also shared information on 'Revised Guidance for Industry: Review of Drug Names for Look-Alike Sound-Alike (LASA) Attributes'; comment period for this consultation document closes on April 19, 2013. This guidance applies to biologic and pharmaceutical drugs (prescription and non-prescription) for human use in which a brand name is proposed (innovator and generic), and does not apply to natural health products.

The Therapeutic Products Directorate's involvement in the Regulatory Cooperation Council (RCC) with the US-FDA and the Regulatory Cooperation Initiative (RCI) with the Therapeutic Goods Administration's (TGA), Australia as part of the International Collaboration initiative was also shared.

5.2 Update on status of repeal of Schedule F

C. Bouchard provided an update on this topic, which had been discussed during the December 2-3, 2012 meeting. Health Canada has released the proposed regulatory changes to repeal Schedule F and replace it with a ministerial list they are calling the Prescription Drug List (PDL). A guidance document and a draft PDL were released at the same time. The consultation period ends on March 7, 2013 and NAPRA will be providing comments. NAPRA is preparing to make the changes

necessary to align the National Drug Schedules (NDS) with these regulatory changes.

5.3 Update by Consumers Association of Canada representative

J. Sayer discussed certain matters that she noted since the last meeting. She first confirmed the scheduling status of a drug that she had seen sold in the self-selection area of a pharmacy. She then shared the fact that although the NDS places pack size restrictions on certain drugs, she has noted that these smaller pack sizes are being sold under “Buy one, get one free” promotions which the committee may need to consider in the future.

6.0 Next meeting

Tentatively set for June 9-10, 2013.

7.0 Adjournment

A motion to adjourn was put forward by Dr. Bailey and approved by consensus. The meeting was adjourned at 11:59am.