A meeting of the National Drug Scheduling Advisory Committee (NDSAC) was held on Sunday, December 8, 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 – Natural Health 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

1.0 Call to order

1.1 Opening remarks

K. McInnes welcomed everyone and called the meeting to order at 9:02 a.m. on December 8, 2013.

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

A motion to approve the agenda as presented was put forward by Dr. Marra, seconded by Dr. Bailey and approved by consensus.

3.0 Approval of the minutes from the March 4, 2013 meeting

A motion to approve the minutes from the NDSAC meeting of March 4, 2013 as posted on the NAPRA website was put forward by D. Dunford, seconded by Dr. Bailey 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 in all package sizes, except for package sizes of 100 or more.

The committee reviewed and considered the application for drug scheduling. 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 welcomed representatives from Boehringer Ingelheim via teleconference: Ms. Samar Darwish, Director of Regulatory Affairs and Drug Safety; Ms. Geethi Gill, Regulatory Affairs Manager and Dr. Nico Landes, Medical Advisor. Boehringer Ingelheim representatives gave a short slide presentation to the committee regarding the request for unscheduled status for bisacodyl 5mg tablets and 10mg

suppositories in all package sizes, except for package sizes of 100 or more, 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 first acknowledged the labelling changes made by the sponsor to improve the information provided to the consumer in the dosage and caution section on the outer carton of the product.

Members discussed the use of bisacodyl in relation to the approved indications for use outlined in the product monograph, which are "for the relief of occasional constipation" and "under medical supervision, for the preparation of diagnostic procedures in pre- and postoperative treatment, and in conditions which require defecation to be facilitated". Members noted the labelling changes made by the sponsor to strengthen warnings not to exceed the recommended daily dose or use for more than a week unless directed by a doctor. Members acknowledged the fact that bisacodyl is not indicated for chronic use, but noted that the information provided by the sponsor indicates that constipation can be a recurrent condition. For instance, the information received indicates that two-thirds of sufferers experience constipation on a monthly basis. In light of the fact that constipation can be a recurring condition, members felt that consumers should have access to a health care professional such as a pharmacist to monitor and provide advice. With regard to the other approved indication for bisacodyl, members acknowledged the information added to the dosage section of the outer labelling to use as directed by a doctor for colonoscopy or other medical procedures. Nevertheless, members agreed that individuals using the product for bowel preparation should have access to a pharmacist to ask questions or request advice.

Although members acknowledged the sponsor's effort to add additional warnings to the outer labelling, they felt it important that consumers have access to a healthcare professional to clarify what the various warnings mean for that patient's particular situation. Members also noted that the potential interaction with proton pump inhibitors (PPIs) and H_2 receptor blockers was not mentioned on the outer labelling. Overall, members agreed that the availability of a pharmacist to expand on drug interactions and bowel preparation instructions and explain labelling information that may not be easily understood by consumers could help promote safe and appropriate use of the drug.

Members discussed the potential for misuse or abuse of bisacodyl. It was noted that there is evidence in the literature documenting the existence of a problem of abuse and misuse of stimulant laxatives such as bisacodyl that can be attributed to their pharmacological action. Members agreed that although not indicated for chronic use, the chronic misuse or abuse of bisacodyl, or its use in a recurrent fashion without the advice of a healthcare professional, could delay recognition or mask the symptoms of serious disease. Members felt that monitoring of inappropriate use would be facilitated in a pharmacy environment with trained staff and pharmacist oversight.

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

- #II-5, #III-1, #III-3, #III-4 and #III-5.

Members acknowledged the sponsor's efforts to modify the labelling of bisacodyl to provide more information to consumers at the point of sale, but concluded that overall, these changes did not affect the applicability of the scheduling factors for this drug. In addition, information newly received from the sponsor led to the applicability of an additional factor compared to a previous review. However, when members considered the labelling changes in the context of acute treatment only and the particularities of this product (e.g. drug interactions with PPIs and H_2 receptor blockers and indication for use as a bowel preparation), they felt that the changes could allow for the possibility of access in an unscheduled environment for package sizes appropriate to the dosage and duration of treatment for acute use of on average 5 days. Although not requested by the sponsor in this manner, members agreed that tablets of up to 5mg and suppositories of up to 10mg in package sizes of less than 50mg could be granted unscheduled status, with all other strengths and package sizes being retained in Schedule III.

MOTION: It was moved by Dr. Zed, seconded by K. Abbass**: to recommend that bisacodyl - when sold in concentrations of 5mg or less per oral dosage unit or 10mg or less per rectal dosage unit/suppository in package sizes containing no more than 50mg of bisacodyl - be granted Unscheduled Status and that bisacodyl and its salts [<u>except</u> when sold in concentrations of 5mg or less per oral dosage unit or 10mg or less per rectal dosage unit/suppository in package sizes containing no more than 50mg of bisacodyl] - be retained in Schedule III.**

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 Natural Health Products Directorate

Dr. R. Bose shared information on the recent transition of the Non-prescription Drug Evaluation Division and Disinfectants Unit from the Therapeutic Products Directorate to the Natural Health Products Directorate that took place on July 1, 2013. An update on the current work to align requirements and practices for products that carry a similar level of risk in the marketplace was shared.

Dr. R. Bose also shared information on '*Protecting Canadians from Unsafe Drugs Act (Vanessa's Law), Bill C-17*', 'Health Products Prescription Drug List', Plain Language Labelling initiative and the GUI-0104 Good Manufacturing Practices (GMP) Guidelines for Active Pharmaceutical Ingredients (APIs).

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

Schedule F changes

S. Marshall provided an update on this topic. As mentioned by Dr. Bose, the regulatory changes to repeal Schedule F and replace it with a ministerial list

termed the Prescription Drug List (PDL) come into effect on December 19, 2013. S. Marshall shared information received from Health Canada on how it intends to notify NAPRA when drugs are added or removed from the PDL. She indicated that sponsors will be encouraged not to submit an application until Health Canada has issued a final Notice of Decision, as the committee would not be able to finalize its recommendation until the final Health Canada decision and final Health Canada approved labelling were available.

5.2 Health Canada consultation on three switches

S. Marshall informed members that Health Canada recently published Notice of consultations for the removal of certain strengths and forms of three (3) drug molecules from the PDL. The deadline for comments on these three switches is January 18, 2014. Members were informed that it was likely that submissions would be received for these molecules for the next meeting. It was confirmed that a maximum of two (2) submissions would be entertained at one meeting, on a first come, first served basis.

6.0 Election of vice-chair

K. McInnes called for nominations for the position of Vice Chair of NDSAC.
K. Abbass nominated Dr. Marra for the position of Vice Chair, seconded by Dr. Zed. No other nominations were received. All members voted in favour of the appointment of Dr. Marra as Vice Chair of NDSAC.

As their terms on the committee were now at an end, K. McInnes, on behalf of NDSAC and NAPRA, thanked K. Abbass and Dr. Zed for all their work on the committee and presented them with a plaque in recognition of their service. She explained that a thank-you note and plaque would also be sent to G. Bradley in recognition of her service on the committee, as Ms. Bradley resigned from the committee for personal reasons this past summer.

7.0 Next meeting

Tentatively set for March 9-10, 2014.

8.0 Adjournment

The meeting was adjourned at 1:46 p.m. (ET).