

A meeting of the National Drug Scheduling Advisory Committee (NDSAC) was held on Sunday, December 2 and Monday, December 3, 2012 at the Lord Elgin Hotel, Ottawa.

Present:

NDSAC members:

Kathy McInnes (Vice Chair and Acting Chair for this meeting); Kim Abbass; Dr. Tom Bailey; Dr. Sheldon Koven; Dr. Nancy MacDonald; 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 9:35 a.m. on December 2, 2012 and welcomed everyone, specifically new member Dr. Tom Bailey.

1.2 Conflict of interest declarations

K. McInnes called for conflict of interest declarations. Members completed and submitted NDSAC conflict of interest declaration forms to her. 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. Koven and approved by consensus.

3.0 Approval of the minutes from the September 11-12, 2011 meeting

A motion to approve the minutes as circulated electronically to Committee members and posted on the NAPRA website was put forward by K. Abbass and approved by consensus.

3.1 Action items update

C. Bouchard reviewed the action items from the previous minutes. C. Bouchard reported on follow-up from Item 5.1 of the September 11-12, 2011 meeting: Guidelines for Schedule Status Submissions. She informed members that the requirement to receive Health Canada reviewer's notes where applicable had not yet been added to the NAPRA website. She also reported that the website would be updated to request that the drug status in foreign jurisdictions include, at a minimum, the major OECD countries and Quebec. The inclusion of actual use studies or recent periodic safety update reports would be considered for addition to the submission guidelines as part of the overall review of the NDS program. C. Bouchard also reported on follow-up from Item 6.1 of the

Sept 11-12, 2011 meeting: NAPRA Draft Updated Natural Health Product Policy. She informed the committee that the Board maintained its decision that Natural Health Products (NHPs) are not considered products for scheduling within the National Drug Schedules (NDS). However, as an interim measure, NHPs currently listed on the NDS will be maintained.

4.0 Review of NDSAC procedure

C. Bouchard provided a quick review of NDSAC Bylaws and Rules of Procedure. It was noted that it is important to make sure the NDSAC members are informed of the final decisions on drug scheduling made by the NAPRA Executive Committee. It was noted that the scheduling factors were last reviewed in 2008 and that as experience is gained with the application of these factors, another revision may be triggered in the future. Discussion also took place on the management of confidential material.

5.0 New Business

5.1 Request for Schedule III status for Dimeticone 100 cSt Solution, 50% w/w as a topical treatment of scalp hair in case of infestation with head lice (pediculosis capitis)

The committee reviewed and considered the application for drug scheduling, as well as additional material made available to them via an external drug information service. No requests for interested party status and no comments via the alternate method of participation were received for this review.

At 1:30pm on December 2, 2012, K. McInnes introduced and welcomed a representative from Pediapharm Inc: Mr. Benoit Hébert, Vice President, Business Development and Licensing. Mr. Hébert gave a short presentation to the committee regarding the request for Schedule III status for Dimeticone 100 cSt Solution, 50% w/w, 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 they reviewed indicated that this drug appeared to be effective and relatively safe, with little or no possibility of the development of resistance. Members discussed the fact that the drug may best be sold in a pharmacy where the pharmacist is available to counsel not only on this drug, but also on all the other aspects of care required for the treatment of head lice. Members discussed the possible volatility of the drug, but noted that product labelling did provide warnings in this regard. Members noted that the product is listed as a medical device in other countries, but R. Bose explained that this drug did not meet the Health Canada definition of a medical device and did meet the Health Canada definition of a drug. It was noted that a warning not to use the drug in children under 2 years of age and in pregnancy or breastfeeding was not included on the outer packaging of the drug. However, warnings not to use the drug in pregnancy and breastfeeding were included in

the package insert and the dosage section on the outer packaging did include instructions for use in children over 2 years of age only. In addition, members noted that the materials reviewed did not show any evidence of serious adverse effects in these subpopulations. The warnings appeared to be based on the absence of data in these subpopulations and not on any specific risks. Members noted that the inclusion of the Health Canada Therapeutic Product Directorate reviewer's report in the application was greatly appreciated and highly valuable. Although drug cost is not under the purview of NDSAC, members did briefly discuss the cost of the drug compared to other available products.

K. McInnes led the group in a review of the applicability of the National Drug Scheduling Factors. The committee agreed that the availability of the pharmacist to provide advice could help patients select the appropriate product, use the product appropriately and deal appropriately with cases of head lice recurrence. It was agreed that the following scheduling factors were applicable to dimeticone 100 cSt solution, 50% w/w as a topical treatment of scalp hair in case of infestation with head lice (*pediculosis capitis*):

- #II-10, #III-2, #III-3 and #III-5.

Members agreed that considering the weight of each applicable factor, the schedule that best fit this drug was Schedule III.

MOTION: It was moved by Dr. Marra, seconded by Dr. Koven to recommend that:

Dimeticone 100 cSt solution, 50% w/w as a topical treatment of scalp hair in case of infestation with head lice (pediculosis capitis) be granted Schedule III status.

Motion carried. All members agreed to the above noted motion. This recommendation will be reported to the NAPRA Executive Committee.

Following this decision, there was discussion on the exact wording to be used for the listing of this drug on the NDS.

MOTION: It was moved by Dr. Bailey, seconded by Dr Koven that the wording for the listing of this drug on the NDS be shortened as follows:

Dimeticone 100 cSt solution, 50% w/w for topical use in the treatment of head lice.

Motion carried. All members agreed to the above noted motion. This recommendation will be reported to the NAPRA Executive Committee.

6.0 Updates

6.1 Health Canada Scientific Advisory Committee on Nonprescriptions Drugs: NAPRA participation

C. Bouchard provided an update on her participation as a member of the Health Canada Scientific Advisory Committee (HC-SAC) on Nonprescription Drugs. The committee is newly formed and has met on three occasions to discuss such topics as draft changes to Part III of the low dose acetylsalicylic acid (ASA)

product monograph, co-packaging of products in certain acne treatment kits, draft guidance documents on application for drug switches from prescription to non-prescription status and look alike, sound alike drugs. C. Bouchard directed NDSAC members to the Health Canada website where agendas and minutes of the HC-SAC on Nonprescription drugs are posted for more information.

6.2 Therapeutic Products Directorate

Dr. Bose provided an update from the Therapeutic Products Directorate (TPD) of Health Canada. TPD has been working on a number of projects since the last NDSAC meeting. Product labels and monographs for low dose ASA and ibuprofen are being revised to reflect the possible inhibitory effect of ibuprofen on ASA's cardio-protective effects. The labelling standard for non-prescription ASA has been revised, the comment period is over and the final document will soon be released. A new draft guidance document on review of drug names for look-alike/sound-alike attributes is expected to be released for consultation early 2013. Dr. Bose briefly shared information related to the Government of Canada's plan for a simpler and quicker process for making changes to the Canadian list of prescription drugs (Schedule F listing in the *Food and Drug Regulations*). A draft guidance document for applications to switch drugs from prescription to non-prescription status is under development. TPD has also been reviewing the Health Canada's New Drug List (dated 1999) and the revised listing of drugs currently regulated as 'New Drugs' and Notice has just been posted on the HC website. Furthermore, Dr. Bose shared ongoing international initiatives such as Regulatory Cooperation Council (RCC) with the United States Food and Drug Administration (FDA) and Regulatory Cooperation Initiative (RCI) with the Therapeutic Goods Administration (TGA), Australia that relates to non-prescription drug products.

7.0 Presentations

7.1 NAPRA Strategic Framework 2012-2015

C. Bouchard provided members with an overview of NAPRA's strategic framework for 2012-2015.

7.2 NDS Review

C. Bouchard provided members with an update on NAPRA's review of the NDS program. This project to review the NDS program began in 2011. The first phase of the project is complete and next steps are currently underway.

8.0 Health Canada presentation on Schedule F changes

On December 3, 2012, K. McInnes welcomed Mr. David K. Lee, Director, Health Canada Office of Legislative and Regulatory Modernization and Mr. Eric Ormsby, Manager, Health Canada Office of Science. Mr. Lee gave a presentation on the recent changes to the *Food and Drugs Act* to allow for the replacement of Schedule F to the *Food and Drug Regulations* with an administrative list. He reviewed the steps currently underway by Health Canada as well as next steps. A question and answer period with Mr. Lee and Mr. Ormsby followed.

9.0 Election of Chair and/or Vice Chair

C. Bouchard led the election of Chair and Vice Chair.

Chair: C. Bouchard called for nominations for the position of Chair of NDSAC.

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

Vice Chair: C. Bouchard called for nominations for the position of Vice Chair of NDSAC.

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

Following the election, C. Bouchard, on behalf of NAPRA, thanked Dr. Koven and Dr. MacDonald for their service on the committee and presented them with a plaque in recognition of their service.

10.0 Next meetings

10.1 Confirmation of tentative dates for 2013 NDSAC meetings

The committee members have agreed to the following dates for 2013:
March 4-5; June 9-10; September 8-9; December 8-9

10.2 Next meeting

Tentatively set for March 4-5, 2013

11.0 Adjournment

The meeting was adjourned at 10:43am on Monday, December 3, 2012.