A meeting of the National Drug Scheduling Advisory Committee (NDSAC) was held on Sunday, June 8 and Monday, June 9, 2014 at the Lord Elgin Hotel, Ottawa.

Present:

NDSAC members:

Kathy McInnes (Chair)(Sunday only); Dr. Tom Bailey; Drena Dunford; Dr. Deborah Kelly, Dr. Carlo Marra (Vice Chair), Judy McPhee, Kendra Townsend

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

Regrets:

Dr. Murray Brown

1.0 Call to order

1.1 Opening remarks

K. McInnes welcomed everyone and called the meeting to order at 9:03 a.m. (ET) on June 8, 2014.

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 K. Townsend, seconded by T. Bailey and approved by consensus.

3.0 Approval of minutes

3.1 Approval of the minutes from the March 9-10, 2014 meeting

A motion to approve the minutes from the NDSAC meeting of March 9-10, 2014 as posted on the NAPRA website was put forward by C. Marra, seconded by J. McPhee and approved by consensus.

3.2 Approval of the minutes from the May 15, 2014 teleconference

A motion to approve the minutes from the NDSAC teleconference of May 15, 2014 as posted on the NAPRA website was put forward by T. Bailey, seconded by D. Dunford and approved by consensus.

4.0 Follow-up matter

4.1 Wording of NDS listing for diclofenac 1.16%

S. Marshall reviewed the motion for topical diclofenac from the May 15, 2014 teleconference. It was clarified that members intended the third part of the motion to include concentrations of 1.16% or less as opposed to concentrations of exactly 1.16%

only. It was determined that this intention would be conveyed to the NAPRA Executive Committee with a recommendation that the NDS listing be amended accordingly.

MOTION: It was moved by T. Bailey, seconded by K. Townsend**: to recommend that the final recommendation for diclofenac diethylamine in concentrations of 1.16% be amended as follows: Diclofenac diethylamine, when sold as a single medicinal ingredient for topical use on the skin in concentrations of not more than 1.16% for not more than 7 days remain Unscheduled.**

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

This recommendation will be reported to the NAPRA Executive Committee.

5.0 New Business

5.1 Request for Schedule III status for omeprazole delayed release tablets 20mg for the treatment of frequent heartburn for 14 days.

The committee reviewed and considered the application for drug scheduling. No requests for interested party status were received for this review. One set of comments that recommended Schedule II status for package sizes of more than 280mg was received via the alternate method of participation.

At 10:15 a.m. on June 8, 2014, K. McInnes welcomed representatives from PendoPharm Inc.: Ms. Geneviève Giroux, B.Pharm., M.Sc., MBA, Director Market Access & Reimbursement and Ms. Sophie Tanguay, M.Sc., Senior Director, Global Regulatory Affairs. The PendoPharm representatives gave a short slide presentation to the committee regarding the request for Schedule III status for omeprazole delayed release tablets 20mg for the treatment of frequent heartburn for 14 days, 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.

The committee first discussed concerns regarding the drug interaction information in the product labelling. It was noted that certain contraindicated drug interactions, such as risedronate DR and rilpivirine, were missing from the product information entirely. As these are examples of relatively new drug interactions and it takes time for product information including labelling to be updated, the committee concluded that current information on drug interactions needs to be provided at product selection. This was a significant concern for a drug with a high potential for drug interactions even with 14 days of use and for which certain drug interactions continue to be investigated. The committee also noted that no drug interaction information is provided on the outer label of this product, thus patients would not receive drug interaction information prior to purchase. Members agreed that a pharmacist is required to review a patient's drug profile and provide up-to-date drug interaction information to patients before purchase.

In addition to the absence of drug interaction information on the outer box, it was noted that a number of other warnings were missing from the outer label, such as not to use in pregnancy and lactation or in the presence of certain cardiac symptoms. While

warnings not to use in the presence of some alarm symptoms such as difficulty swallowing were included on the outer box, other important alarm symptoms such as unexplained weight loss were missing from the outer label. Members concurred that a pharmacist is required to expand on this limited information on the outer label and to assist patients with proper self-selection, particularly in light of the fact that this is not only a new ingredient, but the first of a new drug class for non-prescription use in Canada. The committee also agreed that a pharmacist is required to expand on limited information in the product information about the increased risk of infections.

Members discussed the long-term use of omeprazole. Members were of the opinion that even if used within the approved dosing parameters, if a patient were to regularly use the product every 4 months, this should be monitored by a pharmacist to ensure referral for assessment for more serious conditions, to warn of the risks of long-term use and to ensure that the patient's drug profile reflects omeprazole use. In addition, members were concerned about the possibility of inappropriate and chronic use of omeprazole. The committee noted that omeprazole is indicated for chronic use on prescription and is often required long-term. Members remarked that some of the least well understood information in the Canadian Label Comprehension study was that a 14 day course should only be repeated every 4 months. The committee also noted that there is a body of literature describing the inappropriate use of proton pump inhibitors. Members agreed that a pharmacist is required to monitor for inappropriate, chronic or recurrent use.

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 omeprazole when sold for the 14-day treatment for frequent heartburn at a daily dose of 20mg.

- #I-6, II-2, II-7, II-8, II-9, II-10, III-1, III-2, III-3 and III-5

Overall, the committee agreed that the best fit is Schedule II in view of the drug profile and the need for a limited duration of use as a non-prescription product requiring support from a pharmacist to expand on several aspects of the product information.

MOTION: It was moved by C. Marra, seconded by T. Bailey**: to recommend that omeprazole or its salts, when sold for the 14-day treatment for frequent heartburn at a daily dose of 20mg, in package sizes of no more than 280mg of omeprazole - be granted Schedule II status.**

The committee agreed that package sizes of more than 280mg would be listed in Schedule I.

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

This recommendation will be reported to the NAPRA Executive Committee.

5.2 Request for Schedule III status for triamcinolone acetonide aqueous nasal spray (55mcg per metered spray) for adults and children 12 years of age and older.

The committee reviewed and considered the application for drug scheduling. No requests for interested party status and no comments via the alternate method of participation were received for this review.

At 2:00 p.m. on June 8, 2014, K. McInnes welcomed representatives from Sanofi-Aventis Inc.: Ms. Angelina Habimana, M.Sc., Manager, Regulatory Development; Ms. Melanie Groleau, B. Pharm., M.Sc., RAC., Medical Advisor and Ms. Anne Tomalin, President, Therapeutic Products Inc. The Sanofi representatives gave a short slide presentation to the committee regarding the request for Schedule III status for triamcinolone acetonide aqueous nasal spray (55mcg per metered spray) for adults and children 12 years of age and older, 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.

The committee noted that this medicinal ingredient will be the first nasal corticosteroid spray available without a prescription in Canada. The committee discussed at length information regarding drug interactions as well as the effect on bones and growth in children and adolescents. The committee noted that the product information elaborated sufficiently on these aspects. However, a pharmacist should be available to emphasize the importance of using the lowest effective dose and avoiding other corticosteroids in order to minimize the risks of long-term concerns with this class of drug. The committee felt this was particularly important in light of the lack of available information about the effect on growth in children and adolescents 12 years of age and older.

The committee was also of the opinion that a pharmacist should be available to assist patients in differentiating between the common cold or flu and allergic rhinitis and in choosing an appropriate treatment for their individuals needs amongst the large number of over the counter treatment options available for these conditions. The committee also noted that the instructions for use were quite lengthy and certain aspects were not well understood in consumer studies. Members were of the opinion that some patients may need additional explanation and support from the pharmacist in understanding how to use the product, particularly the need to prime and re-prime the spray and the importance of pointing the spray away from the middle of the nose to decrease the risk of nasal septum perforation. Members discussed the fact that allergic rhinitis is a persistent condition, that can be either chronic if symptoms are perennial or recurrent if symptoms are seasonal. It was agreed that a pharmacist should be available to emphasize that the product should not be used for more than 6 months without consulting a healthcare professional and to provide advice to patients using the drug long-term. A pharmacist should be available to monitor these patients for significant side effects and review and reinforce important product information, as some patients may not re-read the patient insert or labelling with each purchase.

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 triamcinolone

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

The committee agreed that the best fit for the product is Schedule III however, it was suggested that package sizes be limited so that it may provide additional opportunities for discussions between the patient and pharmacist in situations of longer periods of use of the product.

MOTION: It was moved by K. Townsend, seconded by J. McPhee**: to recommend that, subject to removal from the Prescription Drug List by Health Canada, triamcinolone acetonide in an aqueous nasal spray that delivers 55mcg per metered spray for adults and children 12 years of age and older, in package sizes containing no more than 120 metered sprays - be granted Schedule III status and triamcinolone acetonide in an aqueous nasal spray that delivers 55mcg per metered spray for adults and children 12 years of age and older, in package sizes containing more than 120 metered sprays - be granted Schedule II status.**

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

This recommendation will be reported to the NAPRA Executive Committee.

5.3 Request for Schedule III status for minoxidil foam 5% for topical use for female androgenetic alopecia (follow-up matter from March 9-10, 2014)

The committee reviewed and considered the application for drug scheduling. No requests for interested party status and no comments via the alternate method of participation were received for this review.

At 10:00 a.m. on June 9, 2014, C. Marra welcomed representatives from Johnson & Johnson Inc.: Mr. Sam Bottner, Sr. Manager Regulatory Affairs and Ms. Philloza Suleman, Sr. Manager Regulatory Affairs. The Johnson & Johnson representatives gave a short slide presentation to the committee regarding the request for Schedule III status for minoxidil foam 5% for topical use for female androgenetic alopecia. 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.

The committee discussed the applicability of the scheduling factors for minoxidil foam 5% for female pattern hair loss, which is a condition that is new to self-selection in Canada and thus the ingredient is new for women to self-select. Members discussed whether a pharmacist should be available to help patients with appropriate self-selection and help them identify when to stop the medication. The role of the pharmacist in managing patient expectations for this drug and providing clarification on potentially confusing directions for use was also discussed. The committee noted discrepancies in the Product Monograph that the sponsor offered to correct and requested additional information that the sponsor offered to send following the meeting. The committee decided to defer its interim recommendation until it has received and reviewed the requested information and revised Product Monograph.

6.0 Updates

6.1 Natural Health Products Directorate (including Non-prescription Drugs Evaluation Division)

Dr. R. Bose updated on the current work on labelling updates of Levonorgestrel-containing emergency contraception products. This action was taken in response to the European Medicine's Agency announcement on January 14, 2014 that it had started a review of levonorgestrel-containing emergency contraceptives "to assess whether increased bodyweight and body mass index (BMI) reduce the efficacy of these medicines in preventing an unintended pregnancy following unprotected sexual intercourse or contraceptive failure". This was followed by the issuance of a similar statement by Health Canada on January 30, 2014 which stated: "Health Canada evaluating whether body weight affects the effectiveness of emergency contraceptive pill."

Dr. R. Bose also shared information on the Drug Identification Number (DIN) to Natural Product Number (NPN) transfer of hydrocortisone topical preparations containing 1% or less of hydrocortisone. The Notice of Consultation to remove from prescription status was posted by Health Canada.

Dr. R. Bose also shared information on the Products at the Cosmetic-Drug Interface (PCDI). This WG was re-launched between NHPD and HECSB. The group is currently developing Product Assessments Against Criteria (PAAC) documents for anti-dandruff and sunscreen products.

7.0 Election of Chair and 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. Carlo Marra put forth his candidacy for the position of Chair. No other nominations were received and Dr. Marra was acclaimed as Chair of NDSAC.

Vice Chair: C. Bouchard called for nominations for the position of Vice Chair of NDSAC. Dr. Tom Bailey put forth his candidacy for the position of Vice Chair. No other nominations were received and Dr. Bailey was acclaimed as Vice Chair of NDSAC.

As her term on the committee is ending in August, C. Bouchard, on behalf of NDSAC and NAPRA, thanked K. McInnes for her work on the committee over the past years and particularly for her efforts as Chair for the past two years, and presented her with a small token of appreciation in recognition of her service.

8.0 Next meeting

Tentatively set for September 7-8, 2014.

9.0 Adjournment

The meeting was adjourned Monday, June 9, 2014 at 12 p.m. (ET) on a motion by J. McPhee, seconded by D. Kelly and agreed to by all members.