A meeting of the National Drug Scheduling Advisory Committee (NDSAC) was held on Tuesday, March 8, 2016 at the Lord Elgin Hotel, Ottawa.

Present:

NDSAC members:

Dr. Carlo Marra (Chair); Dr. Murray Brown, Ms. Drena Dunford; Dr. Melanie Johnson, Dr. Deborah Kelly, Ms. Judy McPhee, Ms. Kendra Townsend

Observers:

Dr. Ratna Bose – Natural and Non-prescription Health Products Directorate, Health Canada
Ms. Joan Sayer – Consumers Association of Canada

NAPRA Staff:

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

Regrets:

Dr. Tom Bailey (Vice Chair)

1.0 Call to order

1.1 Opening remarks

C. Marra welcomed everyone and called the meeting to order at 9:11 a.m. (ET) on March 8, 2016.

1.2 Conflict of interest declarations

C. Marra called for conflict of interest declarations. Ms. Dunford explained that she recently co-authored a continuing education on allergic rhinitis sponsored by Rogers Healthcare Group. The committee agreed that this did not represent a conflict of interest. Dr. Marra reported that he is in discussions with GlaxoSmithKline (GSK) regarding a research grant that is not related to any GSK product including the drug under review, but relates to a respiratory topic. It was agreed that this may represent a perceived conflict of interest. Therefore, it was agreed that Dr. Marra would abstain from the votes related to the GSK product.

2.0 Approval of the agenda

A motion to approve the agenda as presented was put forward by K. Townsend, seconded by D. Kelly and approved by consensus.

3.0 Approval of minutes

3.1 Approval of the minutes from the December 6-7, 2015 meeting

A motion to approve the minutes from the NDSAC meeting of December 6-7, 2015 as posted on the NAPRA website was put forward by J. McPhee, seconded by D. Dunford and approved by consensus.

4.0 New Business

4.1 Request for Schedule III status for fluticasone propionate aqueous nasal spray 50 mcg/metered dose, for package sizes containing up to 120 metered sprays.

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 10:15 a.m., C. Marra welcomed representatives from GlaxoSmithKline Consumer Healthcare Inc. (GSK) : Mr. Aman Bhatti, Director Medical Affairs, Ms. Stella Chan, Senior Regulatory Affairs Manager and Ms. Erin Oliver, Switch Regulatory Director. The GSK representatives gave a short slide presentation to the committee, 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 presentation and the subsequent question and answer period.

The committee discussed the drug interaction that is known to occur between ritonavir and fluticasone nasal spray. Overall, the committee agreed that this is a serious drug interaction which presents a risk to consumers, but that the labelling could mitigate the risk. However, since the labelling directs consumers to ask a doctor or pharmacist if they are taking an HIV medication such as ritonavir, it was agreed that a pharmacist must be available to answer questions about the interaction, assist patients in determining whether or not they can safety use the drug and reinforce the seriousness of the interaction for patients taking ritonavir.

Members agreed that the availability of a pharmacist would help to promote safe and appropriate use of this drug which is new to the non-prescription setting. The committee noted that some patients may benefit from receiving additional support from the pharmacist to confirm that they are suffering from allergic rhinitis, help them choose the most appropriate treatment among the vast array of non-prescription products for allergic rhinitis and provide further information and education on how to appropriately prime, use and clean the nasal spray device to optimize treatment efficacy and reduce the risk of serious adverse reactions such as nasal septum perforation. It was agreed that a pharmacist could also clarify and reinforce the onset of benefit and the instructions for decreasing the dose after the first week of treatment, as well as help patients determine how to proceed if the lower dose is not effective for them. Members agreed that a pharmacist could also reinforce the age range for the product, which differs from that of other non-prescription intranasal corticosteroids, and reinforce the importance of stopping use if symptoms do not improve within 7 days. Since allergic rhinitis is usually a persistent or chronic condition, it was agreed that a pharmacist must be available to reinforce the appropriate duration of use and monitor and refer patients who may need to use the drug longer than 3 months. After much discussion, it was agreed that pharmacist intervention is not required in all cases, but that a pharmacist should be available to assist patients with self-selection, monitor and refer patients who may need to use the drug long-term and reinforce, clarify or expand on information in the product labelling, as required for the patient's circumstances.

C. Marra 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 fluticasone propionate aqueous nasal spray 50mcg/metered spray, for package sizes containing up to 120 metered sprays.

- #I-6, II-10, III-2, III-3 and III-5

The committee discussed the overall best fit for the scheduling of this substance. It was agreed that the best placement for this drug would be Schedule III, but that package sizes of more than 120 metered sprays should be placed in Schedule II to provide additional opportunities to monitor and refer patients who may need to use the drug long-term.

MOTION: It was moved by K. Townsend, seconded by M. Johnson to recommend that: **fluticasone propionate, when sold for the treatment of allergic rhinitis in a nasal spray that delivers 50 mcg/spray for those 18 years of age and older, in package sizes containing no more than 120 metered sprays, be granted Schedule III status, subject to removal from the Prescription Drug List and**

fluticasone propionate, when sold for the treatment of allergic rhinitis in a nasal spray that delivers 50 mcg/spray for those 18 years of age and older, in package sizes containing more than 120 metered sprays, be granted Schedule II status, subject to removal from the Prescription Drug List.

Motion carried. All members agreed to the above noted motion with one abstention as explained in section 1.2.

This recommendation will be reported to the NAPRA Executive Committee.

5.0 Follow-up matters

5.1 Follow-up to request for

- Schedule III status for a modified-release oral dosage form that provides 600 milligrams of ibuprofen (200 mg Immediate Release(IR)/400 mg Extended Release(ER)) or less per dosage unit for package sizes containing more than 31,200 milligrams of ibuprofen.

- Unscheduled status for a modified-release oral dosage form that provides 600 milligrams of ibuprofen (200 mg Immediate Release(IR)/400 mg Extended Release(ER)) or less per dosage unit for package sizes containing 31,200 milligrams or less of ibuprofen .

This request was reviewed during the December 6-7, 2015 meeting. Although the scheduling recommendation from that meeting was deferred only to ensure that the product monograph and product labelling reviewed by the committee were the final Health Canada approved documents, the scheduling applicant undertook to file with Health Canada changes to this material while the committee was awaiting the final decision of Health Canada regarding the removal of the drug from the Prescription Drug List. Therefore, the committee was required to review the changes made to the product monograph and labelling prior to finalizing its recommendation.

Members acknowledged the addition of a warning not to chew, crush or dissolve the tablets on the outer label and the package insert for the product. In addition, the committee noted the addition of further information to the package insert about the actual dose received when using this modified-release form of ibuprofen. The committee agreed that these changes will provide information that will be of benefit to the patient. However, as the information about the actual dose received over 12 hours is not available to patients prior to purchase, the committee agreed that the changes did not alter their view about the potential for confusion in product selection. Overall, the committee agreed that these labelling changes, while beneficial to the patient, did not alter the committee's original reasoning that a pharmacist should be available to patients purchasing this drug, as described in the meeting minutes of the December 6-7, 2015 NDSAC meeting. Therefore, the committee agreed to confirm the draft motion made at the December meeting.

MOTION: It was moved by D. Dunford, seconded by D. Kelly, to recommend that: **ibuprofen or its salts, when sold in a modified-release oral dosage form that provides 600 mg or less per dosage unit - be granted Schedule III status, subject to removal from the Prescription Drug List**

Motion carried. All members agreed to the above noted motion with one abstention: M. Brown, for reasons explained in section 1.2 of the minutes of the December 6-7, 2015 meeting.

It was further moved by D. Dunford, seconded by D. Kelly: **to recommend that the current National Drug Schedules listings for ibuprofen be amended for clarity once the modified release product becomes listed, to specify that they only apply to immediate release products.**

Motion carried. All members agreed to the above noted motion

These recommendations will be reported to the NAPRA Executive Committee.

5.2 Follow-up to request for Schedule III status for esomeprazole 20 mg (as esomeprazole magnesium trihydrate) when sold for the 14-day treatment for frequent heartburn at a daily dose of 20 milligrams in package sizes containing up to 840 milligrams of esomeprazole

This request was reviewed during the December 6-7, 2015 meeting. At that time, the scheduling recommendation was deferred only to ensure that the product monograph and product labelling reviewed by the committee were the final Health Canada approved documents. Following Health Canada's confirmation of its final decision to remove this drug from the Prescription Drug List, the final product monograph and product labelling were received and there were no differences between the final documents and the documents reviewed by the NDSAC. Therefore, the committee agreed to confirm the draft motion made during the December 6-7, 2015 meeting.

MOTION: It was moved by J. McPhee, seconded by D. Dunford to recommend that:

- **esomeprazole or its salts, when sold for the 14-day treatment for frequent heartburn at a daily dose of 20 mg, in package sizes of no more than 280 mg of esomeprazole - be granted Schedule II status, subject to removal from the Prescription Drug List and**
- **esomeprazole or its salts, EXCEPT when sold for the 14-day treatment for frequent heartburn at a daily dose of 20 mg in package sizes of no more than 280 mg of esomeprazole - be retained in Schedule I following removal from the Prescription Drug List**

Motion carried. All members agreed to the above noted motion with one abstention: M. Brown, for reasons explained in section 1.2 of the minutes of the December 6-7, 2015 meeting.

This recommendation will be reported to the NAPRA Executive Committee.

6.0 Updates

6.1 Natural and Non-prescription Health Products Directorate

Dr. R. Bose provided an update on the most recent technical discussion regarding acetaminophen, as well as on the draft revised acetaminophen labelling standard. She also shared information on discussions regarding non-prescription codeine products. The committee was informed that Health Canada held a few pre-discussions regarding potential switches from prescription to non-prescription status, but has not received formal submissions for these potential switches. Regulatory requirements with respect to the Plain Language Labelling that will be coming into force on June 13, 2017 for non-prescription drugs were also discussed. The directorate has been working on draft drug product fact tables which are expected to be posted for stakeholder consultation this summer.

7.0 Next meeting

Tentatively set for June 6-7, 2016.

8.0 Adjournment

The meeting was adjourned at 1:38 p.m.