A meeting of the National Drug Scheduling Advisory Committee (NDSAC) was held on Monday, June 6, 2016 at the Lord Elgin Hotel, Ottawa.

**Present:**

**NDSAC members:**

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

**Observers:**

Ms. Joan Sayer – Consumers Association of Canada

**NAPRA Staff:**

Carole Bouchard – Executive Director
Sarah Marshall – Manager, Professional and Regulatory Affairs, Committee Secretary
Mr. William Lickley - 3rd year pharmacy student on work term with NAPRA, University of Waterloo

**Regrets:**

Dr. Ratna Bose – Natural and Non-prescription Health Products Directorate, Health Canada

## 1.0 Call to order

### 1.1 Opening remarks

C. Marra welcomed everyone and called the meeting to order at 9:04 a.m. (ET) on Monday, June 6, 2016.

### 1.2 Conflict of interest declarations

C. Marra called for conflict of interest declarations. J. McPhee explained that it was the Deputy Ministers of Health of the provincial/territorial governments that asked Health Canada to consider removing naloxone from the Prescription Drug List and that she works directly under the Deputy Minister of Health in her province. The committee discussed and agreed that this did not represent a conflict of interest.

## 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 8, 2016 meeting

A motion to approve the minutes from the NDSAC meeting of March 8, 2016 as posted on the NAPRA website was put forward by D. Dunford, seconded by D. Kelly and approved by consensus.

## 4.0 New Business

### 4.1 Request for Schedule II status for naloxone hydrochloride, when indicated for emergency use for opioid overdose outside hospital settings

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

At 9:45 a.m., C. Marra welcomed representatives from Health Canada: Ms. Kimby Barton, Interim Senior Executive Director, Therapeutic Product Directorate; Ms. Anne Decrouy, Manager, Central Nervous System Division; Ms. Taranum Singh, Product Evaluation Officer, Bureau of Cardiology, Allergy and Neurological Sciences and Mr. Jean-Charles Guimond, Assessment Officer, Central Nervous System Division. The Health Canada representatives gave a short slide presentation regarding the Benefit-Harm-Uncertainty review of naloxone conducted by Health Canada to inform their consideration of its removal from the Prescription Drug List for certain indications. The Health Canada representatives remained to answer questions for the committee following the presentation.

At 10:30 a.m., C. Marra welcomed the representative from Sandoz Canada Inc. : Ms. Julie Landry, Manager Regulatory Compliance, Scientific Affairs. The Sandoz representative 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 presentations and the subsequent question and answer periods.

It was first noted that naloxone represents a unique situation, as its change to non-prescription status was initiated by Health Canada in response to a public health issue as articulated by the provincial/territorial governments.

Members were generally in agreement that adjunctive therapy and evaluation are necessary following the administration of naloxone to a victim of opioid overdose, including contacting emergency medical services (911), as well as rescue breathing and/or chest compressions, supportive measures such as placing the victim in the recovery position and staying with the victim following administration to evaluate the need for subsequent doses if the first dose is not effective or overdose symptoms return. There was some debate as to whether the need for adjunctive therapy and evaluation is due to naloxone itself or the opioid overdose, but the majority of members agreed that the need to monitor for effectiveness and rebound toxicity are linked to the use of the drug.

The information presented to the committee confirmed that wider access to naloxone in the community setting can save lives and that members of the public can learn to administer naloxone safely if they are provided with appropriate training and education. However, there was no information to suggest that users can learn to safely administer naloxone on the basis of the product labelling alone. The product labelling did not undergo user testing or any form of label comprehension study. In addition, the committee noted several potential concerns with the product labelling, particularly with Part III of the product monograph. Members noted a few discrepancies, were concerned about the public's ability to understand all of the signs and symptoms of opioid overdose, felt that further clarification about the age range of the product is required and agreed that additional information on recognition and management of acute opioid withdrawal syndrome is required. Further, the committee noted that the labelling does not adequately address the handling and disposal of used needles, syringes, vial and ampoules and does not provide sufficient warning about the risks of needle-stick injury, how to avoid needle-stick injury and what to do in case of needle-stick injury. It was determined that a pharmacist is required to clarify and expand on information in the product labelling.

Overall, the committee was of the opinion that pharmacist intervention is necessary in order to provide the training and education required for members of the public (bystanders) to learn how to safely administer naloxone in the community setting or to confirm that the user has received such training and education through a provincial/territorial program. A

pharmacist can ensure that users understand how to recognize the signs and symptoms of opioid overdose for a condition that is new to assessment in the non-prescription setting. Naloxone is currently only available in Canada in an injectable dosage form that requires drawing up the appropriate dose from a vial or an ampoule. Therefore, the committee determined that a pharmacist is required to ensure that users are trained and educated on the proper administration of naloxone, including proper technique, appropriate dose, use of appropriate supplies and how to avoid and manage needle-stick injury, which are not well covered in the labelling. Members agreed that it is important for a pharmacist to emphasize the need to call emergency services (911), as reports from existing take home naloxone programs in the United States and Canada show that 911 was called only ~10-60% of the time. There was also some concern about delays in receiving appropriate follow-up from health professionals to monitor for complications or rebound toxicity if users do not call 911. In addition, a pharmacist can emphasize the need to remain with the victim to provide supportive measures and evaluate the need for subsequent doses. The committee also agreed on the importance of pharmacist intervention at each subsequent purchase of naloxone, to review the training and education points for a drug that is not used regularly, as well as act as a resource for information regarding opioid dependency. Some of the reports reviewed by the committee suggested that illicit drug use actually decreased following participation in take home naloxone programs in the United States, which authors attributed to the education and training provided. Finally, the committee agreed that a pharmacist is required to emphasize the increased risks of naloxone use in neonates and thus the importance of calling 911 and obtaining health professional assistance as soon as possible in this population.

C. Marra led the group in a review of the applicability of the National Drug Scheduling Factors. It was determined that the following scheduling factors were applicable to naloxone hydrochloride injection, when indicated for emergency use for opioid overdose outside hospital settings:

- #I-2, II-3, II-4, II-6, II-9, II-10, III-2 and III-5

The committee discussed the overall best fit for the scheduling of this drug which is new to the non-prescription setting. While the committee had a few concerns about the completeness of the product labelling, the dosage form of the drug, as well as the need for adjunctive therapy, the weight of factor #II-3 (the drug must be readily available under exceptional circumstances when a prescription is not practical) was such that all agreed that a Schedule I placement would not be appropriate. The committee noted that the approval of other dosage forms of naloxone that are more conducive to bystander/self-administration would contribute to the safe use of naloxone in the community setting and encourages Health Canada to examine this matter. In addition, the committee felt it important that there be consistency between Part III of the product monograph and the education/training provided to users in accordance with provincial/territorial guidance documents and take home naloxone programs. It was agreed that suggestions to strengthen the product labelling be forwarded to the manufacturer and Health Canada for consideration. However, the committee acknowledged that its recommendations must be based on the product information and labelling currently in front of them. Overall, the committee determined that the above-mentioned points could be addressed by pharmacist intervention to reinforce the need to call 911 and to ensure that users fully understand the information in the product labelling and receive the training and education required for safe administration of naloxone in the community setting. The committee trusts that the on-going work of provincial/ territorial governments and health profession regulators, particularly pharmacy regulators, will contribute to ensuring that naloxone users receive the necessary training and education. It was therefore agreed that Schedule II would be the best fit for injectable naloxone.

**MOTION:** It was moved by T. Bailey, seconded by K. Townsend to recommend that:

**Naloxone hydrochloride injection, when indicated for emergency use for opioid overdose outside hospital settings, 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.

## 5.0 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. Tom Bailey was nominated and agreed to put forth his candidacy for the position of Chair. No other nominations were received and Dr. Bailey was acclaimed as Chair of NDSAC.

**Vice Chair:** C. Bouchard called for nominations for the position of Vice Chair of NDSAC. Ms. Kendra Townsend was nominated and agreed to put forth her candidacy for the position of Vice Chair. No other nominations were received and Ms. Townsend was acclaimed as Vice Chair of NDSAC.

As this was his last meeting, C. Bouchard, on behalf of NAPRA, thanked C. Marra for his work on the committee and particularly for his contribution as Chair over the past two years, and presented him with a small token of appreciation in recognition of his service.

## 6.0 Next meeting

Tentatively set for September 12-13, 2016.

## 7.0 Adjournment

The meeting was adjourned at 2:24 p.m (ET).