

A meeting of the National Drug Scheduling Advisory Committee (NDSAC) was held on Sunday, September 11 and Monday September 12, 2011, at the Lord Elgin Hotel, Ottawa.

Participants

Committee members

Dr. Ruth Wilson, Chair; Kathy McInnes, Vice Chair; Kim Abbass; Gail Bradley; Dr. Nancy MacDonald; Dr. Sheldon Koven; Dr. Peter Zed; Dr. Carlo Marra

Observers

Dr. Ratna Bose – Therapeutic Products Directorate, Health Canada
Joan Sayer – Consumers Association of Canada

Staff

Carole Bouchard – NAPRA, Executive Director
Kathy Vesterfelt – NAPRA, Manager, Professional and Regulatory Affairs, Committee Secretary

1.0 Call to order

1.1 Call to Order

Dr. Ruth Wilson called the session to order at 9:00 a.m. and welcomed everyone to the meeting.

1.2 Conflict of interest declarations

The Chair called for conflict of interest declarations. Dr. MacDonald indicated that she had worked for one of the companies that had been granted Interested Party status. However, her employment with the company ended upon her retirement seven (7) years ago. The committee members did not feel that this represented a conflict of interest. No other members had anything to declare.

2.0 Approval of the agenda

The agenda was approved as circulated.

3.0 Approval of the minutes March 6, 2011

The minutes were approved as circulated electronically to Committee members and posted on the NAPRA website.

4.0 New Business

- 4.1** A drug scheduling review was initiated at the request of NAPRA, for the nonprescription nonsteroidal anti-inflammatory drugs (NSAIDs), excluding ASA and acetaminophen, currently available on the Canadian market. The primary intent of the drug scheduling review of these NSAIDs will be to determine if the current NDS scheduling remains appropriate.

The committee reviewed and considered the submission report prepared by an independent consultant, as well as materials made available to the committee through the Interested Party process and alternate method of participation.

The committee was informed that Interested Party status was granted to seven organizations for this agenda item. Three companies or organizations elected to make a presentation before the Committee.

At 10:00 a.m. K. Vesterfelt welcomed representatives from Consumer Health Products Canada: David Skinner, President and CEO, Gerry Harrington, Director of Public Affairs and Leonard Baum, Vice-President, Regulatory Affairs, North America from Bayer, Inc. The committee members then introduced themselves. Mr. Harrington made a presentation to the committee which was followed by a period of questions and answers.

At 11:00 a.m., representatives from Bayer Inc. Consumer Care made a presentation before the committee. Attending on behalf of Bayer Inc. Consumer Care were, Leonard Baum, Joseph Chan, Regulatory Affairs Manager and Neil Hamilton, Market Research Consultant, Principal, Alexandra Consulting. The presentation was followed by a period of questions and answers.

At 1:15 p.m. K. Vesterfelt welcomed representatives from Pfizer Consumer Healthcare. Dr. Murray Brown, Vice-President Scientific Affairs, Dr. Walid Aldoori, Medical Director and Ms. Hilary Schinkel, Director Regulatory Affairs made a presentation to the committee which was followed by a period of questions and answers.

Following the presentations, the committee had a long discussion around the materials and information provided to them pertaining to the over-the-counter (OTC) NSAIDs that were included in this drug scheduling review.

From the information the committee received, the data indicates the risk of serious adverse events remains low for oral OTC NSAIDs when used for approved indications at approved dosing for the approved duration of use. However, the literature indicates that the rate of adverse drug events (ADE) for OTC oral NSAIDs is higher as the dose increases and with longer duration of use. In addition, the committee further commented that ADEs are significantly under-reported not only for this class of drugs but for all drugs.

The committee members expressed concerns about the potential impact of the inappropriate use (e.g. doses exceeding the maximum daily dose, longer duration of use or chronic use) of oral OTC NSAIDs, particularly in a subset of the populations such as the elderly or those with co-morbid diseases.

The Committee members noted that specific independent research is needed to investigate whether package size and place of sale influence the appropriate use for drug products; in this instance, OTC oral NSAIDs. However, despite the relative scarcity of documented evidence made available to the committee regarding the influence of package size and place of sale on the appropriate use of OTC oral NSAIDs, there was consensus of the expert and professional opinion of the NDSAC members that the potential for inappropriate use of oral NSAIDs exists. Segments of the population, particularly the elderly and those who have co-morbid diseases or those with cardiovascular and gastro-intestinal (GI) risk factors may be at particular risk of adverse events by inappropriate use of OTC oral NSAIDs. These consumers could benefit from the availability of a health care practitioner such as a pharmacist to seek advice from and to provide clarification on questions they may have regarding the appropriate selection

and use of OTC oral NSAIDs. The committee acknowledges that product labeling follows Health Canada standards and provides a source of information to consumers with regard to the safe and appropriate use of drug products. However, it is also reported that product labels are not read at all times and that some consumers can not always appropriately self-assess the risk of using a product relative to their own medical situation.

Each drug molecule was reviewed one after the other starting with Ibuprofen.

Ibuprofen

A review of the applicability of all scheduling factors was led by the Chair. It was agreed that the following Scheduling Factors for oral ibuprofen were applicable: Schedule #I-4, #1-6, #II-2, #III-3 and #III-5.

NDSAC recommends maintaining unscheduled status for ibuprofen, but at a minimum limiting the maximum unit doses in packages so that it is more appropriate in relation to approved labeled indication, dosage and duration of use. Larger packages would be available from a pharmacy. This would provide a mechanism that the consumer can seek advice from the pharmacist, which is especially important in the context of a persistent, chronic or recurring condition which may require a health professional intervention.

It was moved by Dr. Zed, seconded by Dr. Marra that:

Ibuprofen and its salts containing ≤ 400 mg per oral dosage unit (when sold in package sizes of up to 18,000 mg) remain Unscheduled and,

Ibuprofen and its salts containing ≤ 400 mg per oral dosage unit (when sold in package sizes exceeding 18,000 mg) be changed from Unscheduled to Schedule III.

While Dr. MacDonald abstained, no members were opposed to the motion.

Motion carried.

To be reported to NAPRA Executive Committee.

Naproxen sodium

A review of the applicability of all scheduling factors was led by the Chair. The approach taken was to apply the scheduling factors to the product based on the current NDS scheduling status.

It was agreed that scheduling factors #1-4, #1-6 and #II-10 applied to packages sizes up to 6,600 mg and that factors #I-4, #I-6, #II-2, #II-10, #III-2, #III-3 and #III-5 remain applicable for package sizes exceeding 6,600 mg.

It was moved by K. Abbass, seconded by K. McInnes that:

Naproxen sodium 220 mg per oral dosage unit (when sold in products labeled with a recommended maximum daily dose of 440 mg, and in package sizes of up to 6,600 mg) remain Unscheduled status and,

Naproxen sodium 220mg per oral dosage unit (when sold in products labelled with a recommended maximum daily dose of 440 mg, and in package sizes exceeding 6,600 mg) remain Schedule III.

All committee members were in favour of this motion.

Motion carried.

To be reported to NAPRA Executive Committee.

Topical diclofenac

A review of the applicability of all scheduling factors was led by the Chair. The approach taken was to apply the scheduling factors to the product based on the current NDS scheduling status.

It was agreed that only scheduling factor #III-5 was applicable.

It was moved by G. Bradley, seconded by C. Marra that diclofenac diethylamine in preparations for topical use on the skin in concentrations of not more than the equivalent of 1% diclofenac remain Unscheduled.

All committee members were in favour of this motion.

Motion Carried.

To be reported to NAPRA Executive Committee.

5.0 Business arising from previous meeting

5.1 Guidelines for Schedule Status Submissions

The Chair led the members in a discussion of this agenda item, by initially reviewing the draft guidelines for drug scheduling submissions. The draft guidelines were prepared some years ago by previous NDSAC members.

It was agreed that this draft document will not be implemented and that more discussion is warranted. The members expressed their views that it is not in their mandate to provide further scrutiny of Health Canada's authority to determine the safety, quality and efficacy of drug products through the drug approval process.

However, the members feel that a few items presented in the draft Guidelines may be useful to improve the current content of drug scheduling submissions to NDSAC. For example, having access to the Health Canada reviewer's notes for a particular product could be useful in the Committee's deliberations. It was acknowledged that this matter will be again addressed if there is a comprehensive NDS review.

In the interim and for future submissions, the NDSAC members asked that in addition to the requirements outlined on NAPRA's website, Health Canada reviewer's notes be included where applicable as part of the information requested in a Drug Scheduling Submission. Furthermore, the NDSAC members wish to ensure that the drug status in

other countries include, at a minimum, scheduling comparisons from Organization for Economic Co-Operation and Development (OECD) countries. This part of the submission has to also include the scheduling in the province of Québec which utilizes a separate scheduling system.

If these above-mentioned items were not available, an explanation would be required as part of the submission

The following were also suggested as elements to consider requesting:

- Actual Use Studies
- Recent Periodic Safety Update Report

6.0 Updates

6.1 NAPRA draft updated Natural Health Product Policy

C. Bouchard informed the members that NAPRA is finalizing a consultation with stakeholders regarding the proposed updated *Policy for Natural Health Products (NHPs)*. The NHP policy was reexamined by a NAPRA Working group at the request of the NAPRA Board of Directors. Following a fulsome review and deliberation of the Working Group's findings, the Board expressed their intention to maintain the decision previously made which means that the NHPs are outside the scope of the National Drug Schedules. The result of the consultation will be reviewed by the Board of Directors for consideration. A final decision on the Policy will be forthcoming.

6.2 NDS review - Phase 1 Consultation

C. Bouchard indicated that Phase 1 of the National Drug Schedules began this year and consists of documenting the program history, undertaking an environmental scan and consulting a wide range of stakeholders regarding the program. Consultants were hired by NAPRA to conduct Phase 1. Their results are expected to be reviewed by the Board of Directors at their upcoming meeting. Dr. R. Wilson will be interviewed by the consultants.

6.3 HC-Scientific Advisory Committee on Nonprescription Drugs

C. Bouchard informed the members of Health Canada initiative to create a new Scientific Advisory Committee on Nonprescription drugs (SAC-NPD). The mandate of this committee was shared with the NDSAC members for information. It was also reported that NAPRA has been invited to participate as a core member. C. Bouchard will be the NAPRA representative on SAC-NPD.

7.0 For information

7.1 Therapeutic Products Directorate update

Dr. R. Bose informed the Committee on the US-FDA public advisory committee meeting on paediatric use of acetaminophen which was held on May 17-18, 2011.

Dr. R. Bose also shared information on the voluntary change announced by the McNeil Consumer Healthcare, division of McNeil- PPC, Inc. in the U.S. to move to (1) a single concentration of acetaminophen for single ingredient Infants' and Children's TYLENOL® products sold in the U.S., and (2) plans for lowering the maximum daily dose for single-ingredient Extra Strength TYLENOL® (acetaminophen) products from 8 pills per day (4,000mg) to 6 pills per day (3,000mg) to help encourage appropriate acetaminophen use and reduce the risk of accidental overdose. However, the McNeil Consumer Healthcare division of Johnson & Johnson Inc. (Canada) announced that there will be no such change to products sold in Canada.

Health Canada is currently evaluating Canadian-based information or data streams related to paediatric acetaminophen product use and safety considerations.

Dr. R. Bose shared with the Committee the fees with respect to drugs and medical devices that came into effect on April 1, 2011, and also the Regulatory proposal for 'Non-medicinal Ingredients Labelling (NMI) (SOR/2010-105)' that has been made into regulations and are published in Canada Gazette Part II.

8.0 Other Administrative issues

8.1 Tentative dates for NDSAC meetings 2012

The committee members have agreed to the following dates for 2012:
March 4-5; June 17-18; September 9-10 and December 2-3.

9.0 Date of next meeting

Tentatively set for December 4-5, 2011.

10.0 Adjournment

The meeting was adjourned at 2:30 p.m. on Monday, September 12, 2011.