



**Health Canada - Health Products and Food Branch (HPFB)
Bilateral Meeting Program**

Record of Decisions

Canadian Society of Hospital Pharmacists (CSHP)

1600 Scott Street, Holland Cross, Tower B, 2nd Floor, Boardroom 2048, Ottawa, Ontario

Thursday, March 11, 2010

(1:30 p.m. to 2:45 p.m.)

Canadian Society of Hospital Pharmacists Participants

Myrella Roy, Executive Director, CSHP, Co-Chair

Richard Jones, Past President and Internal Liaison, CSHP and Director of Pharmacy Services

London Health Sciences Centre, London, Ontario

Health Canada Participants

Barbara J. Sabourin, Senior Executive Director, Therapeutic Products Directorate (TPD), Co-Chair

Denis Arsenault, Office of Controlled substances (OCS), Healthy Environments and Consumer Safety Branch (HECSB)

Bruce Boulton, Bureau of Gastroenterology, Infection and Viral Diseases (BGIVD), TPD

Marcin Boruk, Bureau of Policy, Science and International Programs (BPSIP), TPD

René-Pierre Charron, Marketed Health Products Directorate (MHPD)

Edward Gertler, Office of Pharmaceuticals Management Strategies (OPMS), Strategic Policy Branch

Gail Gervais, Liaison Unit, Office of Business Transformation (OBT), TPD

Adam Gibson, Director General's Office (DGO), TPD

Luna Al-Khalili, MHPD

Janet Kramer, MHPD

Lisa Lange, BPSIP, TPD

Robert Liteplo, MHPD

Denise Quesnel, Liaison Unit, OBT, TPD

Marilyn Schwartz, Submission and Information Policy Division (SIPD), TPD

Teleconference

Chantelle Ladner-Holmes, Natural Health Products Directorate (NHPD)

Observers

Lisa Brochu, MHPD

Myriam Wallet, SIPD, TPD

Regrets

Supriya Sharma, Director General, TPD

1. Welcome and Introductions

Barbara J. Sabourin, Senior Executive Director, Therapeutic Products Directorate (TPD) welcomed the attendees and extended Dr. Supriya Sharma's regrets.

Dr. Myrella Roy, Executive Director, CSHP, thanked TPD for the opportunity to meet. She expressed Jason Howorko's regrets. Mr. Howorko is the current CSHP President and External Liaison.

A roundtable of introductions followed.

2. Review of Agenda

The Agenda was approved.

3. Approval of the March 5, 2009 Meeting Notes

Approved as presented.

Review of Action Items from March 5, 2009

Item 9. Update on Notice of Compliance with Conditions (NOC/c) Policy and Guidance Revisions

Lisa Lange, Associate Director, BPSIP, TPD, noted that the document was in the process of being finalized. It is expected to be posted by the end of April, 2010 for a 60-day comment period. She invited CSHP to provide comments on the guidance including the Dear Healthcare Professional Letter (DHPL) templates. CSHP will be notified through the stakeholders' distribution list.

Marcin Boruk, Senior Policy Analyst, BPSIP, TPD, mentioned that there will be a DHPL template for generic products in the revised NOC/c guidance document. There are also three generic drugs approved under the NOC/c policy for which DHPLs have been posted and are available for viewing on the Health Canada's website.

Post Meeting Update - Due to additional internal comments and the need to format the document for posting, it will not likely be posted for comment until the middle of June 2010.

4. Change in Licensing Status from Drugs to Natural Health Products

Chantelle Ladner-Holmes, Policy Analyst, Bureau of Policy and Regulatory Affairs, NHPD, provided clarification on labelling for products containing iron.

Ms. Ladner-Holmes mentioned that NHPD's policy toward the labelling of mineral supplements is consistent with the TPD Labelling Standard and Category IV Monograph for mineral supplements, which have the identical labelling instruction. The quantitative declaration of a mineral must be made using the chemical name and quantity of the element provided by the source, as well as the name of the source, as follows: Calcium (calcium lactate).....x mg, and to be compliant with the TPD Labelling Standard, the label of the NPN product should read: Iron (ferrous gluconate) 35 mg. Ms. Ladner-Holmes added that NHPD applicants often decide to provide both the elemental quantity and the source material quantity, example-Iron 35 mg (from ferrous gluconate 300 mg).

The inclusion of both elemental quantity and the source material quantity provide more clarity, but is not required by the NHP Regulations as the quantity of elemental iron is interpreted as meeting the requirements under section 5(c)(ii).

Since this approach to labelling has been consistently applied for many years, and industry is completely in tune with it, there is no justification to change that approach. As long as mineral products are consistently labelled as providing for example 35 mg of elemental iron, consumers will not be confused as all other authorized products on the market have the same labelling. In this case, the product with the label stating 300 mg is potentially confusing to consumers.

Compliance action is warranted on violative labelling, but not products that follow the Labelling Standard and NHPD requirements.

Please note the risk regarding the labelling of iron-containing products published on the Health Canada website in June 2009 (http://www.hc-sc.gc.ca/ahc-asc/media/advisories-avis/_2009/2009_90-eng.php).

CSHP is welcome to notify the Health Products and Food Branch-Inspectorate (HPFB-Inspectorate) of any iron product that continues to have confusing labelling, so that appropriate compliance actions can be taken to mitigate any potential risk to health.

5. Designation of Pharmacists as Practitioners under the *Controlled Drugs and Substances Act*

Denis Arsenault, Section Head, Policy, Policy and Regulatory Affairs Division, OCS, Health Canada, provided the update on the revision of the regulatory proposal for the *New Classes of Practitioners Regulations* (NCPR).

Mr. Arsenault mentioned that the OCS convened a meeting in July 2009 with representatives from provincial/territorial (P/T) ministries of health to discuss various issues pertaining to the 2007 proposal for the *New Classes of Practitioners Regulations* (NCPR). The meeting was a success, with OCS and P/T participants engaging in constructive discussions on respective roles/ responsibilities and key issues of concern including definitions of classes of health professionals, practitioner requirements, and drug schedules within the proposed NCPR. Participants agreed upon broad principles for the development of a revised Designation Framework (formerly known as the *Policy Framework for Designating Practitioners under the Controlled Drugs and Substances Act*) which will outline the process through which Health Canada will consider including of additional classes of practitioners in the NCPR in the future. It was also agreed that a Federal/Provincial/Territorial (FPT) Working Group (WG) be formed to serve as a forum for further dialogue with P/T ministries of health on the proposed NCPR.

Since this meeting, the FPT-WG on the NCPR has convened twice by teleconference to further discuss matters pertaining to the NCPR. The WG is focussing on the three original key issues (example-definitions of health practitioners, practitioner requirements and drug schedules), and examined a revised version of the Designation Framework.

With regard to the proposed Performance Measurement and Evaluation Plan (PMEP), it was agreed that it would be reviewed and revised as required once a new NCPR proposal has been fully developed.

Myrella Roy, Executive Director, CSHP, welcomes the opportunity for discussions, but emphasized that there are more pharmacists than nurse practitioners in many community settings and that the scope of practice for many pharmacists has changed considerably since the original proposal for the NCPR was pre-published in 2007. As a result, she argued that hospital pharmacists should be given a higher priority for authorization under the NCPR.

Mr. Arsenault noted that the FPT-WG has agreed that relevant stakeholders should be consulted once a revised NCPR proposal and Designation Framework are completed. As a result, OCS is not in a position at this time to discuss the process for the submission and evaluation of proposals for designating additional classes of practitioners under the NCPR.

Action: Mr. Arsenault will bring the priority issue back to the Working Group.

6. MedEffect™ Canada Social Marketing Campaign

René-Pierre Charron, Manager, Outreach and Partnerships Section, Therapeutic Effectiveness and Policy Bureau (TEPB), MHPD, provided the update. He mentioned that a marketing strategy was prepared to assist the MHPD in the development and execution of a multi-faceted national campaign intended to increase the level of reporting of adverse reactions. The campaign targeted both health professionals and consumers from February to May 2009.

The MedEffect™ Canada social marketing campaign addressed professional awareness and engagement about the reporting processes, reinforced the value and benefits of improving the quality of the data reported, and generated increased consumer security that Health Canada has a suite of tools to improve marketed health product safety.

Since the campaign, there has been an increase in voluntary reporting. As it is difficult to measure the direct impact of the campaign, MHPD can not confirm its direct link at the moment.

As part of the partnership agreement, participating pharmacies were asked to send an Evaluation Form. Nine hundred and fifty (950) pharmacies responded to the questionnaire. Participating pharmacists received 5,023 questions on adverse reactions from consumers/patients during the campaign months. The majority of participating pharmacists reported no increase in questions about adverse reactions compared to the same period of the previous year. Participating pharmacists reported 367 adverse reactions during the campaign months. The majority of participating pharmacists reported no increase in adverse reaction reporting compared to the same period of the

previous year. Summarized feedback received regarding the brochure, A Patient Guide for Reporting Side Effects from Health Products, included:

- The brochure contains good information;
- The brochure display is a good size for the counter;
- And the brochure holder falls.

The majority of pharmacists who responded to the questionnaire said that they would participate in the campaign again. MHPD is not planning another campaign at this time; however, outreach/educational activities are ongoing. Mr. Charron invited CSHP to contact him to explore various possibilities or to express its ideas.

7. National Pharmaceuticals Strategy (NPS)

Edward Gertler, Senior Policy Analyst, SPB, extended regrets from Patricia-Anne Côté, Acting Director, Drug Access, Office of Pharmaceuticals Management Strategies, SPB.

With detailed information provided before the meeting, Mr. Gertler provided a brief update on this initiative, on which there was little ensuing discussion. He noted that many of the challenges and issues addressed in the context of the NPS still persist, and that these challenges differ somewhat in the hospital and non-hospital setting. Indicating that Health Canada has ongoing interest in pursuing collaborative approaches to these issues with provincial and territorial partners, he noted however that continued collaboration has been compromised by the provincial and territorial partners' pursuit of additional federal funding, in particular since the release of the NPS Progress Report in 2006.

He noted nevertheless that progress has been made in terms of drug coverage in Saskatchewan, Nova Scotia, and Newfoundland and Labrador, and that program changes by Ontario are saving the province an estimated 20 per cent on generic drugs.

In other areas, Mr. Gertler noted that the continued evolution of the Common Drug Review is an important contribution in moving towards greater pan-Canadian consistency in drug plan formulary listing decision-making. He also stated that the NPS commitment to broaden the practice of e-prescribing through accelerated deployment of the Electronic Health Record has been primarily addressed through the federal government's funding of Infoway, and that this work promises to support optimal drug prescribing and use. In that regard, he noted that in its 2010 budget, the federal government had indicated its plans to release \$500 million in Infoway funding originally earmarked in Budget 2009.

In the area of post-market drug safety and effectiveness, he underscored the establishment of the Drug Safety and Effectiveness Network (DSEN) with \$32 million in federal funding over its first five years, which is being hosted by the Canadian Institutes of Health Research and whose first Executive Director is Robert Peterson, a former Director General of Health Canada's TPD. It was noted that the DSEN initiative represents a range of potential partnering opportunities with the CSHP, including potential research funding opportunities.

Finally, Mr. Gertler noted that Health Canada is working to identify and address key challenges associated with expensive drugs for rare diseases, another element of the NPS. During the discussion, Richard Jones, CSHP, expressed his appreciation for the Health Canada policy statement of December 2007 on the federal regulatory aspects of e-prescribing.

8. Look-alike Sound-alike (LASA) Health Product Names

Luna Al-Khalili, Acting Manager, Patient Safety Section, MHPD, provided a brief update. She mentioned that in January 2006, Health Canada's Guidance for Industry - Drug Name Review: Look-alike Sound-alike (LASA) Health Product Names became effective. This guidance stated Health Canada's expectations and sought to generate consistency in the information submitted by sponsors regarding the impact of a proposed name on the safe use of a biologic or health product.

Internal analysis of LASA-related submissions since the release of the 2006 guidance has revealed significant variation in the amount, type and quality of the evidence submitted by sponsors. This review, along with continuing clinician and consumer concern about medication errors due to LASA names, suggests the need to revisit the 2006 guidance on LASA names.

In October 2008, Health Canada initiated the development of a conceptual framework and a revised guidance document for reviewing newly proposed health product names for LASA similarity. An Expert Panel was created to support this development process, with representation from Health Canada, the United States of America Food and Drug Administration (FDA), the Institute for Safe Medication Practices (ISMP) Canada, psycholinguistic, and a Human Factors Engineer.

The proposed conceptual framework and supporting guidance document will strive to bring greater scientific validity, transparency, objectivity and predictability to the evaluation of health product names for LASA attributes. It is proposed that the framework and guidance will apply to the following product types for human use: prescription and non-prescription drugs, biologics, and natural health products.

Over the next year, efforts will be focused on putting a number of health product names through each step of the proposed name review process to establish "proof of concept".

Marilyn Schwartz, Director, SIPD, TPD, mentioned that SIPD has had technical issues with the Phonetic and Orthographic Computer Analysis System (POCA). She hopes to be able to start the testing of the POCA application in the coming months.

9. Drug Package and Label Design

CSHP would like a plan for the implementation of a proactive process for the monitoring of drug package and label designs. Hospital pharmacists frequently deal with adverse events and near-misses related to poorly designed drug packages and labels.

Bruce Boulton, Assessment Officer, BGIVD, Chair of the Working Group on the Label Guidance, addressed this item. He mentioned that the labelling of drug products must meet the requirements of the *Food and Drugs Act and Regulations* and the policies and guidances related to labelling, available on the (www.hc-sc.gc.ca). All labels must be reviewed by Health Canada before the products are marketed in Canada.

The *Food and Drug Regulations* provide certain information such as what information must be on the label (example- scheduling symbols), where that information should be placed (example-main panel) or the exact wording (example- “sterile”) of some of this information. A template has also been created in a guidance recommending exactly how some information is to be presented (example- Consumer Information template located in the *Guidance for Industry: Product Monograph*).

An initial draft of the *Labelling of Pharmaceutical Drug for Human Use* Guidance is expected to be available for external stakeholders to comment on soon. This guidance document includes references to non-Health Canada guidance documents to which manufacturers may wish to refer to in the design of drug labelling. This includes a reference to the CSHPs’ publication *Drug Packaging and Labelling for Manufacturers (2001)*.

Appendix C to the draft guidance is a list of labelling guidance documents created by third parties that may be of optional interest to drug product sponsors in the creation of drug labelling. Mr. Boulton invited CSHP to create guidelines that could be added to the Appendix. He also identified some of the requirements that should appear on the label. The required information on the label must be legible (pursuant to Section A.01.016 of the *Food and Drug Regulations*) and the specified information must be indicated on the main panel (example- brand name, proper/common name, standard, scheduling symbol and Drug Identification Number (DIN)). The organization and presentation of other information is proposed by the sponsor.

Currently, TPD ensures that all the requirements for labelling as pursuant to the *Food and Drug Regulations* are followed. The “standard” provided by these regulations in conjunction with the additional information provided in draft *Labelling of Pharmaceutical Drug for Human Use* guidance are considered by TPD to provide adequate control with respect to the labelling of drug products. The upcoming release of the draft will provide an opportunity for stakeholders to provide input and suggest means by which Health Canada may better manage risks associated with drug product labelling.

Mr. Boulton mentioned that if CSHP sees a labelling issue, it can approach companies directly for clarification.

10. Roundtable

Barbara J. Sabourin thanked CSHP for the pleasant meeting.

11. Adjournment: Meeting adjourned at 2:45 p.m.

12. Next meeting: Date to be confirmed.

Original signed by

Barbara J. Sabourin
Senior Executive Director
Therapeutic Products Directorate