Health Canada Santé Canada

Health Canada - Health Products and Food Branch
Bilateral Meeting Program
Record of Decisions

Canadian Consumer Specialty Products Association (CCSPA)

1600 Scott Street, Holland Cross, Tower B, 2nd Floor, Boardroom 2048, Ottawa, Ontario
November 29, 2011
(1:30 p.m. to 3:10 p.m.)

CCSPA Participants
Cheryl Fougere, CCSPA, Co-Chair
Heather Barker, SC Johnson and Son, Ltd.
Shan Chaudhuri, Clorox
Taniya Mann, Reckitt Benckiser

Teleconference
Stephen Chambers, Del Tech
Mike Gilbrook, SC Johnson and Son, Ltd.
John Hobbs, Proctor and Gamble (P&G)
Rhonda Jones, Scientific and Regulatory Consultant (SRC)
Melissa Klamerus, Ecolab
Leigh Ann Richardson, Lonza

Health Canada Participants
Barbara J. Sabourin, Acting Director General, Therapeutic Products Directorate (TPD), Co-Chair
Jacques Bouchard, Bureau of Gastroenterology, Infection and Viral Diseases (BGIVD), TPD
Ian Chisholm, BGIVD, TPD
Lucie Desforges, Office of Consumer and Public Involvement (OCAPI)
Gail Gervais, Liaison Unit, Office of Business Transformation (OBT), TPD
Karin Hay, Bureau of Policy, Science and International Programs (BPSIP), TPD
Lisa Lange, BPSIP, TPD
Denise Quesnel, Liaison Unit, OBT, TPD
Sonia Roussel, BGIVD, TPD
Hieu Vu, OBT, TPD
Shannon C. Wright, BGIVD, TPD
Tasha Yovetich, BPSIP, TPD

Observers
Lynn Hefferton, OBT, TPD
Christine Leroux, OBT, TPD
Paul Litowitz, Director General's Office, TPD
Genevieve Moore, Food and Drug Act Liaison Office (FDALO)
Dobrila Todoric, Marketed Health Products Directorate (MHPD)

1. Welcome and Introductions

Barbara J. Sabourin, Acting Director General, Therapeutic Products Directorate (TPD), Health Products and Food Branch (HPFB), welcomed everyone, and a roundtable of introductions followed.

Ms. Sabourin announced the departure of Dr. Supriya Sharma at the end of October. Dr. Sharma has accepted a position at the Ivey Centre for Health Innovation and Leadership at the University of Western Ontario. Ms. Sabourin has accepted to be the Acting Director General until the staffing process is completed.

Ms. Sabourin mentioned that the Auditor General's Report on Pharmaceutical was released on November 22, 2011. The Report is posted on the Auditor General's website.

2. Review of Agenda

Approved.

3. Approval of the Meeting Notes of May 18, 2011

Approved.

Action items from the meeting of May 18, 2011

5. Emerging Pathogens and H1N1 Claims on Public Health Agency of Canada (PHAC) site

Action: Look at Pest Management Regulatory Agency (PMRA)'s database and provide a decision at the November 29, 2011 bilateral meeting.
Update/Action: Cheryl Fougere, CCSPA, will send a proposal to Barbara J. Sabourin, then will discuss off-line. This document was sent on November 30, 2011.

7. "Kills Germs" Claims

Action: To prepare a Notice on the ability for industry to make "Kills Germs" claims - to be posted on the Health Canada website. This issue was discussed under Agenda item 6.

4. Red Tape Reduction Commission

Tasha Yovetich, Senior Policy Analyst, Bureau of Policy, Science and International Programs (BPSIP), TPD, provided the update on how TPD will be responding to CCSPA's submission.

TPD received the list of irritants identified by industry in the spring of 2011 and over the course of the summer has worked on completing response plans which grouped the irritants into one or more of four (4) themes: Performance Standards; Communication; Predictability; and Appropriateness of Regulations. The challenges posed by disinfectants and sanitizers were identified as falling into the response plans addressing predictability in application of regulations and the appropriateness of regulations and were considered within that context.

The response plans were compiled as part of the departmental response to the Treasury Board of Canada Secretariat and ultimately are to be used as input into the Committee's Recommendations, scheduled for release this month. Health Canada anticipates that the issue of disinfectants and sanitizers may be addressed as part of the Regulatory Modernisation process which is currently underway.

The Action Plan will be a separate document which should be launched at the end of this fiscal year. The official report should be launched next month.

5. Status of the Guidance Document Update/Canadian General Standards Board (CGSB) Withdrawal

Shannon C. Wright, BGIVD, TPD, provided the update on this item.

It was noted that cost recovery and regulatory modernization were outside the scope of this initiative.

At this time, TPD can report that the revision/update of the 2007 version of the *Guidance Document (GD): Disinfectant Drugs* is proceeding as planned. A few major revisions have been addressed through informal internal consultations, but which are not yet finalized. Category IV monographs are now proposed to be reverted to stand-alone documents in order to manage their current and future revisions outside the scope of the Guidance Document. Toilet Bowl Cleaners are now proposed to be part of the Hard Surface Disinfectant monograph. The current status of the revision/update is such that input is still being incorporated from consultations with the project's working group (WG) members. The projected timeline for the external consultation period is during the 2nd quarter of 2012.

The draft version will be made available to all stakeholders at the same time during the external consultation period. In the interim, TPD is willing to provide CCSPA with a document which summarizes the WG's comments and recommendations to each of the 60+ questionnaire

responses that were received from CCSPA in March 2011. This would allow CCSPA a "sneak peek" of the resolutions recommended by TPD for each issue that CCSPA specifically identified. The timing for the completion of this document is expected to correspond with the completion of the first draft version of the GD by the WG, which is projected to be during the 1st quarter of 2012.

With regard to the impending withdrawal of the Canadian General Standards Board (CGSB) 2.161-97 standard, TPD would like to notify CCSPA that as of November 2011, it still remains available for purchase through the CGSB website. As indicated at the May 2011 bilateral meeting, TPD does not have any updates from the Standards Council of Canada (SCC) regarding the actual date for which the standard will be withdrawn and for which the status on the CGSB website will be revised to indicate this.

Cheryl Fougere, CCSPA, will be happy to comment on Issue 4. Shannon Wright will send questions to Ms. Fougere, and Ms. Fougere to get back to her in a month or so.

Action: Shannon Wright to send questions to CCSPA.
Update: Materials were sent to CCSPA to initiate discussions on the revision of Category IV Monographs.

6. Unqualified "Kills Germs" Claim/Influenza A

Ian Chisholm, Disinfectants Unit, BGIVD, TPD, addressed this item.

After the bilateral meeting in May 2011, a review was undertaken regarding the "kills germs" issue, given that antimicrobial agents are regulated not only by TPD, but also by Natural Health Products Directorate (NHPD), PMRA, Healthy Environments and Consumer Safety (HECS), and Food Directorate/Canadian Food Inspection Agency (CFIA). During this review, it was noted that there were some inconsistencies, even within TPD itself, as to the approach taken regarding the use of the term "germs" in the labelling of antimicrobial products.

To get a more unified approach, Health Canada proposes that, as part of the revision to the *Guidance Document: Disinfectant Drugs*, Health Canada will look at the use of the term "germs" so that there is greater consistency applied by Health Canada. The rationale for doing it as part of the revision to the Guidance Document is that all of the listed regulatory groups do have membership as part of the Working Group.

Although it is recognized that this may result in some delay in the allowance of qualified "kills germs" claims, the process will also allow for a comprehensive analysis of the usage of the unqualified claims as well. The current intent is also to review the process for approval of the proposed claims, such that the use of the term "germs" may revert to a similar scenario as that

prior to the issuance of the 2007 revision of the *Guidance Document: Disinfectant Drugs* [for example (e.g.): acceptable use of "germs" and "germicide" claims for disinfectant drugs approved through full review and through the Category IV Monograph process]. This would be achieved though the addition of a specific definition for the terms in the revised *Guidance Document: Disinfectant Drugs.*

7. The Organisation for Economic Co-operation and Development (OECD) Meeting Held in Europe

Ian Chisholm, Disinfectants Unit, BGIVD, TPD, provided an update on the meeting that was held in Europe, in September 2011.

The OECD meeting of Experts and Regulators for the Test Guidelines on Microbicides Efficacy took place on September 13 and 14, 2011. Health Canada was a participant at this meeting.

In April 2002, a meeting was held in Washington D.C in which it was decided that new quantitative efficacy methodologies should be developed. The resulting methods, developed by Dr. Syed Sattar, Professor Emeritus of the University of Ottawa, are based on the ASTM E2197 (2002) methodology, a method currently accepted by both Canada and Australia.

In the September meeting, there were some issues raised by industry members, notably regarding the reproducibility of the test method; product form bias; as well active ingredient bias of the methodology. Another issue of relevance was the quality of the test carriers as there is currently only one North American supplier, and more than 90% of the carriers have to be discarded prior to use due to damage.

The United States Environmental Protection Agency (EPA) intends to conduct a collaborative test with laboratories with expertise in conducting disinfectant testing being involved. The tests started in October 2011. The results are expected to be published in June 2012. Depending on the results, the expected date for the approval of the methodologies is late 2013, and more likely 2014. Upon their approval by the OECD, sponsors may submit data using these methodologies to all OECD jurisdictions; however, regulatory bodies may require additional data to be provided. Health Canada will continue to be supportive of the ongoing harmonization efforts, and evaluate the methodologies as further information is made available. The Guidance Document will have to incorporate flexible language to accept the harmonized recognized methods when the OECD methods are finalized.

8. Searchable Label Database

Lisa Lange, Acting Director, BPSIP, TPD, addressed this item.

CCSPA would like Health Canada to have a database with search functions similar to the PMRA database.

As indicated during the May 2011 bilateral meeting, developing a searchable database of approved labels is not a priority for TPD at this time. This is primarily an information technology (IT) issue, and due to other priorities relating directly to performance management and cost recovery, the development of such a searchable database is not currently a departmental priority. TPD does recognize CCSPA's concern and agrees that a searchable database would benefit both industry and staff in the branch, including the HPFB-Inspectorate.

To further this goal, TPD would encourage CCSPA to become a member of the HPFB-industry partnership known as the Group on Electronic Regulatory Activities (GERA). GERA is aimed at advancing the submission and review of electronic information between the regulator and industry by bringing together stakeholders from various health product industries that interact with HPFB. This group works towards identifying and implementing electronic solutions that are common to all stakeholders. More information on this group can be found at GERA Wiki: https://sites.google.com/site/geraprojectwiki/project-team.

TPD also encouraged CCSPA to contact Craig Anderson, Manager of Regulatory Affairs Operations at AstraZeneca to obtain more information on this group.

9. 'Therapeutic Products' versus 'Health Products'

CCSPA heard that another industry has been discussing the desire to change the language in the *Food and Drugs Act* from "health products" to "therapeutic products", and wanted TPD's thoughts on the issue.

Barbara J. Sabourin mentioned that she was not aware of any language change to the *Food and Drug Act*.

10. Pilot Project on Foreign Reviews

Cheryl Fougere, CCSPA, will be in touch with Louise Déry directly after the webinar meeting which is scheduled for December 12. Ms. Déry is the Acting Director, International Affairs Division, Policy, Planning and International Affairs Directorate (PPIAD).

Rx&D will be leading the webinar meeting. Lucie Desforges, Director, Office of Consumer and Public Involvement (OCAPI), will be contacting Rx&D to ensure that CCSPA gets invited to participate.

11. "Top 10" Common Errors Made by Industry

Shannon C. Wright, BGIVD, TPD, addressed this item.

As committed to at the May 2011 bilateral meeting, TPD has prepared a "Top 10" list of the most common errors and deficiencies submitted by manufacturers for disinfectant applications. These have been separated into administrative issues (5) and efficacy and labelling issues (7). This list has been compiled through a high-level review of the screening and review issues previously addressed to manufacturers for disinfectant submissions. This list is an update of the 2006 list that was provided to CCSPA.

Shannon Wright welcomes CCSPA's feedback on the list. Cheryl Fougere will consult with the CCSPA's members and contact Ms. Wright when ready to address issues.

The list will be posted on the CCSPA's website.

Action: Cheryl Fougere will consult with the CCSPA's members and contact Ms. Wright when ready to address issues.
Update: A teleconference was scheduled for the week after the bilateral meeting in which CCSPA outlined its requested revisions to the Frequently Asked Questions (FAQ) document, and for which the revised document will be sent to CCSPA in January 2012 for comments. The revised document was sent to CCSPA as planned, and CCSPA will provide comments to TPD by February 17, 2012.

12. Social Media

As social media is becoming an increasing useful tool for communicating with the public, CCSPA wanted to know if TPD was considering using social media as a means to communicate.

Health Canada uses a number of social media tools to share its content and provide access to reliable and timely health and safety information when, where and how you need it. The links to these Health Canada Social Media Tools can be found on the Health Canada website at http://www.hc-sc.gc.ca/home-accueil/sm-ms/index-eng.php.

TPD recently released its own Real Simple Syndication (RSS) Feeds which publishes new items, such as Guidance Documents, Summary Basis of Decisions for Drugs Products, policies, and forms that are added to the Drug Products section of the website. The link to this RSS can be found on the Health Canada website at http://www.hc-sc.gc.ca/home-accueil/_feed-fils/index-eng.php.

More broadly the department has over 15,000 followers of its Twitter account which is mainly used to "push out" information for the general public (e.g., notices, recalls, announcements). Two Facebook pages are also used to reach out to youth (DrugsNot4Me) and the general public (Healthy Canadians). The Department also has a mobile application to inform the public about recalls and safety alerts. Various videos are also offered on the Health Canada YouTube Channel. Barbara J. Sabourin requested that this item be added to the next bilateral meeting (May 2012) and that the Marketed Health Products Directorate (MHPD) be invited to attend.

Lucie Desforges, Director, OCAPI, mentioned that the HPFB-Inspectorate was working on a site to raise awareness about sales on line. This item will be discussed further at the next bilateral meeting.

Taniya Mann, Reckitt Benckiser, CCSPA, was interested in an update on bar code. Lisa Lange, Acting Director, BPSIP, mentioned that she was aware that some related issues were being discussed at the Branch level. This item will also be added to the next bilateral meeting.

Action: To add the following items to next bilateral meeting, May 2012:

- Social media, Regulatory Unit challenges (Twitter/Facebook) (MHPD);
- Website to raise awareness about sales on line (HPFB-Inspectorate);
- Bar code issue.

13. Round Table

a. **Therapeutic Products Directorate (TPD) Forward Planning Initiatives**
Lisa Lange, Acting Director, Bureau of Policy, Science and International Programs (BPSIP), outlined the initiatives that are currently active and which will require industry input in the near future. Where possible, the anticipated timing of the projects was provided to facilitate the coordination of member input by CCSPA.

b. **Health Canada Website**
Lucie Desforges, Director, OCAPI, mentioned that the Department was reviewing its structure on the website. The plan would be to separate the website and be more tasks oriented. The two websites would cover (1) Healthy Canadians, and (2) Health Canada. The Health Canada website would focus on the needs of departmental stakeholders (industry, health organizations, health professionals etc.) while Healthy Canadians would focus on the general population.

c. **Training Session**
CCSPA would like to organize a training session in connection to the Guidance Document. TPD will provide the content for the session.

d. **Pipeline Forecasting**
Lynn Hefferton, Contracting and Database Officer, Office of Business Transformation (OBT), TPD, provided a heads-up on the pipeline meetings.

CCSPA will be asked to provide data to Health Canada. Using this information, TPD will project future workload for the drug bureaux in a manner similar to the TPD's Workload Management reports (which reflect actual workload). The idea is to develop a template that can be populated by industry and submitted to TPD which can collate all the information received and use it to plan for future workload.

A draft template and instructions has been generated that is based on a simplified Workload Management Forum (WMF) excel spreadsheet. TPD would like to work with CCSPA to refine the approach and template to ensure that quality information can be obtained in a manner that is not overly burdensome to either the industry or TPD. The proposed approach is to have sponsors submit updated pipeline information via the excel template every 6 months (January and July). Knowing that this information can change within the 6 months timeframe, TPD has created an email address to which companies can provide updated information on individual submissions (within certain criteria).

e. **Interface Meeting**
Cheryl Fougere, CCSPA, will be sending the date of the next Interface meeting to Barbara J. Sabourin.

14. Adjournment
Meeting adjourned at 3:10 p.m.

15. Next Meeting
Wednesday, May 16, 2012, at 1:30 p.m.

Original signed by

Barbara J. Sabourin
Acting Director General
Therapeutic Products Directorate