Health Canada Santé Canada

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

Direct Sellers Association (DSA)
1600 Scott Street, Holland Cross, Tower B, 2nd Floor, Boardroom 2048, Ottawa, Ontario
Monday, May 14, 2012
(1:30 p.m. to 3:15 p.m.)

DSA Participants
David Pelletier, Immunotech Research Ltd., Co-Chair
Ross Creber, President, Direct Sellers Association (DSA)
Donna Sweetnam, Arbonne International Canada Inc.
Krystle Gonzalez, Mary Kay Cosmetics Ltd.
Spence Masson, Nature's Sunshine Canada
William Morkel, Dicentra Inc.
Lewis Retik, Gowling Lafleur Henderson Limited Liability Partnership (LLP)
Michael Rowlands, Shaklee Canada Inc.
Jacqui Jensky, Amway Canada Corporation

Health Canada Participants
Barbara J. Sabourin, Director General, Therapeutic Products Directorate (TPD), Co-Chair
John Patrick Stewart, A/Senior Executive Director, TPD
Jacques Bouchard, Bureau of Gastroenterology, Infection and Viral Diseases (BGIVD), TPD
Gail Gervais, Liaison Unit, Office of Business Transformation (OBT), TPD
Lisa Lange, Bureau of Policy, Science and International Programs (BPSIP), TPD
Mary-Jane Ireland, Veterinary Drugs Directorate (VDD)
Sonia Roussel, BGIVD, TPD
Stephanie Reid, HPFB-Inspectorate

Observers
Genevieve Moore, Food and Drugs Act Liaison Office (FDALO)
Marilena Bassi, OBT, TPD
Robert Leitch, Marketed Health Products Directorate (MHPD)

1. Welcome and Introductions

Barbara J. Sabourin, Director General, TPD, HPFB, welcomed everyone, and a roundtable of introductions followed.

a. TPD Organizational Update

Barbara Sabourin provided the following staffing updates at the Directorate level:

Dr. John Patrick Stewart joined the Director General's Office as the new Acting Senior Executive Director.

Heather L. MacDonald is the new Acting Associate Director of BPSIP, TPD.

Marilena Bassi is the new Director of OBT, TPD.

Dr. Barbara Rotter has retired from her position as Director of the Bureau of Metabolism, Oncology and Reproductive Sciences (BMORS).

b. 2012 Federal Budget Update

Barbara Sabourin summarized the impact of the 2012 Federal Budget on TPD. She reported that, while review resources were largely protected, some reductions were required within the Directorate. Some functions within TPD were combined or reorganized to create internal efficiencies. The federal budget decisions translated to a loss of 15 positions within TPD.

The other major change outlined in the budget relates to Schedule F, which will be eliminated and replaced by an administrative list of prescription drugs. The process for drug submissions will be unchanged and all drug submissions to Health Canada will continue to be subject to rigorous scientific assessments. Current processes will be upheld until such time that the changes are published in *Canada Gazette II* and the regulations are updated. It is hoped that these will be ready to implement by spring 2013

c. DSA Update

Ross Creber advised that Robin Bell had retired but was still available to them occasionally.

New addition: Donna Sweetnam and David Pelletier is now the Co-Chair.

Ross Creber advised that industry seemed to weather the recession better than expected but they hope to be returning to a better market this year.

2. Review of Agenda

Approved.

3. Approval of the Meeting Notes of May 31, 2011

Approved.

4. Low Risk Veterinary Health Products

William Morkel, Dicentra Inc., advised that as of March 2012, North American Compendium began receiving applications under the new Notification Program for Low-Risk Veterinary Health Products. This is a welcome development for industry, but the DSA would like feedback as to the ultimate objectives of the program and what they can expect in terms of a final regulatory framework. The intent is to understand the next steps and future intentions concerning regulation of low risk veterinary products in particular and Natural Health veterinary products in general. DSA realizes that this topic may fall under the purview of the VDD (who they are not meeting with) but would appreciate, if the subject could be addressed. An overview of any developments concerning the overall approach on self-care product at the Branch level would be appreciated.

Supporting Documents: Interim Notification Pilot Program for Low-Risk Veterinary Health Products (LRVHPs) - Frequently Asked Questions

Desired Outcome:

That the HPFB will provide feedback on the future course of the program specifically with respect to:

- How long the interim program is expected to run.
- Will the future anticipated regulatory framework expand on the program to permit therapeutic/treatment claims?
- Will Establishment Licensing/Site Licensing requirements for these products be implemented?

Mary-Jane Ireland, VDD, provided a presentation [Overview of Interim Notification Program (INP)] in response to DSA's questions and concerns.

Mary-Jane advised that not all veterinary drugs will fall under INP - that the quality standards won't be applied across product lines. There may be a need to verify lists provided by the Inspectorate to make sure it is made clear.

5. Pharmacovigilence Program and the Post-Market Reporting

Jacqui Jenskey, Amway Canada Corporation, spoke to the number of pharmacovigilance audits that are being performed on drug products today. These are separate from the Drug Good Manufacturing Practices (GMP) Audits and are based on a guidance documents that was written more for pharmaceutical companies, not Category IV Low Risk cosmetic-like Drug products. For example, the following information is required for a prescription medicine and a lip stick with sun protection factor (SPF) 15:

1. A person with a medical background is required to assess if an adverse event (AE) is a serious or non-serious reaction.
2. All companies are required to perform a scientific literature search across to identify any new literature on products/active ingredients. This is in the guidance document to be performed every 2 weeks. However, these products meet the Category IV Monographs and Industry feels it is up to Health Canada to change those documents based on new scientific research.
3. Annual summary reports have to be by drug identification number (DIN) and a person with a medical background must review the summary and write a conclusion. These are low risk products that have monographs.

Some relaxation on these requirements for Low Risk Monographs products would be appreciated.

Stephanie Reid, Manager, Drug GMP Inspection Unit, Inspectorate provided a status update:

The new guidance document entitled "*Post-Market Reporting Compliance Guidelines (GUI-0102)*" was posted for comments on Health Canada's website from July 5 to October 4, 2011. The Post-Market Reporting Compliance (PMRC) working group (WG) reviewed all the comments received from stakeholders. It is currently in the approval process. The posting of the final version of the document and its implementation are expected later this year.

Over-the-counter (OTC) Category IV drugs meet the definition of a drug set out in the Food and Drugs Act, the manufacturers of these product types are responsible for complying with the adverse reaction reporting requirements per the *Food and Drug Regulations* and are covered under the scope of the PMRC inspection program.

The Inspectorate is moving towards a risk-based approach for the selection of sites for inspection. The guiding principle in the selection process is the safety and efficacy of drugs marketed in Canada. The criteria listed below may be considered, but, ultimately, Health Canada must ensure that the greater risk to health is mitigated. The selection of establishment subject to PMRC inspection will be based on a variety of criteria including, but not limited to, those outlined below:

- Compliance of the establishment (facility);

- Date of last inspection;
- Rating of previous PMRC inspections and type of observations that were noted;
- Information on the drug products;
- Therapeutic Class;
- Adverse drug reactions;
- Lateness based on the 15-day regulatory reporting period;
- Type of ADR reports that were reported late.

As well in response to specific concerns Stephanie Reid provided the following responses:

1. In reference to the comment regarding the person who assesses the seriousness of adverse drug reactions, a similar comment was received during the consultation period. Upon revision of the document, it remains that a qualified health care professional's responsibilities include: evaluation of information in respect of a potential adverse drug reaction (ADR), assessment of the seriousness, expectedness, and reportability of an ADR as well as determination of its inclusion in the Annual Summary Report.

   The Inspectorate does not expect all establishments to employ a full-time qualified health care professional. A qualified healthcare professional could be contracted by the manufacturer to perform the abovementioned activities. He/she should be available at any time to fulfill his or her responsibilities in regards to ADR reporting and relevant requirements set out in the Food and Drug Regulations.

2. In reference to the comment regarding the frequency of literature searches, the following is stated in MHPD's guidance document *Guidance Document for Industry - Reporting Adverse Reactions to Marketed Health Products*:

   "It is recommended that the frequency of the literature searches be at least every two weeks. A qualified health care professional from the Market Authorization Holders (MAH) should use their clinical judgment to determine the appropriate frequency of literature searches based on the health product marketed by the MAH".

   Similarly, the Inspectorate's guidance document *Post-Market Reporting Compliance Guidelines (GUI-0102)* will state:

   "The process, including but not limited to how the search is done, the database(s) used, and the periodicity of those searches describing the search in the literature should be written in a procedure. AND

   Searches, on the marketed drug and active pharmaceutical ingredients, in published literature should be performed on a regular basis. Please refer to Section 4.1.3 of the MHPD document "*Guidance Document for Industry - Reporting Adverse Reactions to Marketed Health Products*" for additional information."

3. Please refer to #1.

   Stephanie Reid also thanked those who provided comments on the new guidance document. It is hoped to have this posted later this year followed by implementation.

6. United States Drug Facts on Labels

Jacqui Jensky, Amway Canada Corporation, spoke to this item. When the final United States Food and Drug Administration (FDA) Sunscreen monograph was published there was concern for Canadian companies that they would no longer be able to share labels with the US. On behalf of DSA she indicated their sincere thank you for the cooperation Industry has received through TPD for the development of labels that accommodate the US drug Facts box with the Canadian labelling requirements. They appreciate the support.

Barbara Sabourin mentioned how much we appreciate getting this positive feedback from DSA. We continue to try and collaborate and change our processes to better align with the US.

7. Therapeutic Products Directorate Forward Planning Initiatives

Lisa Lange, BPSIP, TPD provided an update on the several pending TPD initiatives and a handout was circulated.

8. Round Table: No items were brought up.

9. Adjournment: The meeting was adjourned at 2:45 pm

10. Next Meeting: Spring 2013 - to be determined.

Original signed by:

Barbara J. Sabourin
Director General
Therapeutic Products Directorate