

**HEALTH CANADA - HEALTH PRODUCTS AND FOOD BRANCH
THERAPEUTIC PRODUCTS DIRECTORATE
BILATERAL MEETING PROGRAM**

DRAFT SUMMARY OF DISCUSSIONS		
GROUPEMENT PROVINCIAL DE L'INDUSTRIE DU MÉDICAMENT (GPIM)		
LOCATION: 1600 Scott Street, Holland Cross, Tower B, 2 nd Floor, Boardroom 2048, Ottawa		
DATE: Wednesday, May 18, 2005	START TIME: 1:30 p.m.	END TIME : 3:05 p.m.

HEALTH CANADA PARTICIPANTS	ASSOCIATION PARTICIPANTS
<p>Omer Boudreau, Director General, TPD, Chair Siddika Mithani, Associate DG, TPD Diana Dowthwaite, Associate DG, HPFB Inspectorate Jenifer Collette, OBT Gary Condran, BPS Kevin Doyle, OBT Nada El-Defrawy, HPFB Inspectorate Gail Gervais, Liaison Unit, OBT Micheline Ho, SMAB Louise Jodoin, Inspectorate Erin McAlpine, OBT Thea Mueller, SMAB Denise Quesnel, Liaison Unit, OBT Marilyn Schwartz, SIPD, OBT Johanne St-Denis, Inspectorate Hieu Vu, Policy Bureau, TPD Michael Wood, SIPD, OBT Brigitte Zirger, Policy Bureau, TPD</p>	<p>Pierre Morin, DG, GPIM, Co-Chair Stéphane Lévesque, Solumed Jacques Dequoy, SiFi North America</p>

1. Welcome and Introductions

Omer Boudreau, Director General, TPD welcomed the group and a roundtable of introductions followed.

Mr. Pierre Morin presented the book entitled Pharmaceutical Quality to Mr. Omer Boudreau. Mr. Morin was a co-author and is positive that Health Canada would make better use of it.

2. Review of Agenda

The Agenda was accepted with the following corrections:

There was a correction of name – Stéphane Lévesque (not Patry).

Addition to the Agenda: GMP References on Forms (discussed as last item).

There was a change to the Agenda in order to accommodate the schedule of Diana Dowthwaite, Director of the Compliance and Enforcement Coordination Division, Health Products and Food Branch Inspectorate. (Items 7 and 8 were addressed earlier than planned on the Agenda.)

7. Inspectorate Enforcement Activities: Opacity and Responsibilities

The Inspectorate withdrew an Establishment Licence of a testing lab in December and required clients to redo all Quality Control testing on products and did not inform clients of why EL was withdrawn and then reissued EL to the same lab in April. The company understands the process, but no reasons were given for the withdrawal. GPIM indicated that is important to identify why such action is taken. The companies are being asked to review their quality control system.

Diana Dowthwaite, Director of the Compliance and Enforcement Coordination Division, and Louise Jodoin, Health Products and Food Branch Inspectorate explained the process.

In the event that a company does not comply with regulatory requirements, and pursuant to section C.01A.017, “the Minister may suspend an establishment licence without giving the licensee an opportunity to be heard if it is necessary to do so to prevent injury to the health of the consumer (...)”. In such a case, Health Canada could contact the clients of the company to (1) inform them of the inspection and the resulting suspension of the company’s EL, (2) verify if the company contacted them previously and (3) to request an action plan describing what they intend to do in order to remain compliant with the requirements of the *Food and Drugs Act* and *Regulations*. In the mean time, the company may possibly correct deficiencies at their cost. It is the company’s responsibility to ensure that the products are safe, efficient and of good quality for the Canadian market.

If the company requests to be inspected again and if the company is then found to be in compliance with GMP requirements, a new Establishment Licence could be issued. Health Canada could also issue Terms and Conditions pursuant to section C.01A.008 (4), which states: “The Minister may, in addition to the requirements of subsection (2), set out in an establishment licence terms and conditions respecting (a) the tests to be performed in respect of a drug, and the equipment to be used, to ensure that the drug is not unsafe for use; and (b) any other matters necessary to prevent injury to the health of consumers, including conditions under which drugs are fabricated, packaged/labelled or tested.”

The Inspectorate follows similar inspection cycles of pharmaceutical regulators in other jurisdictions, which is 24 months for fabricators, packagers / labellers and testing laboratories and 36 months for importers, distributors and wholesalers. However, taking account of the resources and priorities of the Inspectorate and the schedules of the companies, it is not always possible to meet these inspection cycles. In such cases, the Inspectorate expects that companies are good corporate citizens and do their part to ensure

that their activities comply with applicable regulatory requirements. Responsibility for health and safety of Canadian is shared between healthcare professionals, industry, consumers, government, and other stakeholders.

Public communications are issued when it is deemed necessary to do so in order to mitigate the risks to health (i.e. when a cease sale and recall of the health product would not be sufficient). It is not only dependent on the degree of the potential risk to health to an individual, but largely also on the distribution of the health product. When a severe risk to health is identified for health products administered solely in hospitals, for example, a Dear Health Care Professional Letter (DHCPL) will be issued rather than a communication piece to the general public.

Public communications are often issued in instances where a severe risk to health is identified for health products available directly to the general public (i.e. sold in pharmacies) or when it is conceivable that the health product in question could be in the possession of a consumer (health products ordered via mail order). Such communication pieces are used when the health product in question can be visually identified by the consumer; the communications often urge patients to consult with their pharmacists or health care professionals in order to further correctly identify if the health product in their possession is the one identified as posing a risk to health. Conversely, Public Advisories may advise a consumer to cease taking a health product. The decision to issue a public communication piece and the content of such a piece is assessed on a case by case basis.

Action: The Inspectorate committed to providing a summary of a letter that was provided to companies.

The letter explained that an inspection of a lab was conducted under the authority of the *Food and Drugs Act* (FDA) in order to verify the compliance with Part C, Division 2 of the *Food and Drug Regulations* (FDR), regarding Good Manufacturing Practices. The purpose of the letter was to inform clients that the establishment licence of the lab was suspended as of December 15, 2004, and that all microbiological and chemical testing results and certificates of analysis issued by the lab since March 2001 were considered unreliable. Consequently, the firms that had used the services of this lab were requested to submit in writing a detailed action plan to address the required corrective measures.

8. **Inspectorate Policy Interpretation:**

A modification was brought to policies to the effect that a drug imported into Canada for packaging could only be re-exported to the country of origin.

Some members have developed a good business packaging drugs destined to multi site clinical trials. This modification has eliminated whatever economic advantage was theirs without notice nor consultation notwithstanding the provisions of section 37 of the FDA.

Diana Dowthwaite and Johanne St-Denis referred to the Agenda Item Summary they had prepared. Under section A.01.040 of the *Food and Drug Regulations*, all drugs in dosage form that are imported into Canada for the purpose of sale must comply with the

requirements of the *Food and Drugs Act* (FDA) and *Regulations*, regardless of whether the drug is to be sold to Canadian or to foreign customers. Therefore, if an establishment imports a product into Canada, the establishment is considered to be an importer and consequently must meet the requirements of Division 1A (i.e. list the foreign site on the Establishment Licence) and Division 2 (i.e. perform ID testing and stability testing).

The guideline entitled “Conditions for Provision of Packaging/Labelling Services for Drugs Under Foreign Ownership” was developed by the Inspectorate in order to clarify specific requirements to be met by a Canadian establishment seeking to bring into Canada a shipment of a drug solely to provide contract packaging/labelling services in relation to that drug that is then re-exported to the foreign manufacturer who retains ownership of the drug during such a transaction.

Health Canada did not consult with industry prior to the issuance and implementation of this guideline as the document provides a regulatory exemption to this type of industry.

The document was issued and posted on the Inspectorate Website on May 1st, 2004, and was implemented on June 1st, 2004.

Actions: The Inspectorate to explore the possibility of revising the guideline entitled "Conditions for Provision of Packaging/Labelling Services for Drugs Under Foreign Ownership (GUIDE-0067)".

TPD to meet with the Inspectorate to see if clarification is needed.

** to add to next Agenda.*

3. Review of Action Items: November 17, 2004

Item 4. Old/New Drug Determination

Hieu Vu, Manager, Policy Division, Policy Bureau has been assigned to this file. Part of the file includes assessing the usefulness of the New Drugs List and the need for it to be updated. GPIM is interested to know what the criteria are for a product to be on the list. If unsure of a drug's status, sponsors are advised to contact Dr. Thea Mueller, A/Manager, Non-Prescription Drug Evaluation Division, Senior Medical Advisor Bureau, TPD for a drug status decision before they submit a DIN application (Tel: 613-954-6740).

Item 5. NOC Database (based on the DSTS)

Michael Wood addressed this item. GPIM is pleased to see the new Database for NOCs, but would like it to be extended to DINs. The suggestion will be considered. Marilyn Schwartz, Director of Submission and Information Policy Division (SIPD) stated that after the database is launched, consideration will be given to an enhancement to add the DIN approvals.

Item 6. Follow-up on Good Guidance/Good Review Process

GPIM is pleased with the high level of interest in this initiative. TPD and BGTD undertook internal and external consultations as part of a needs assessment on the GGP and GRP Initiatives. The GGP and GRP Working Groups have prepared two reports, summarizing their respective results from both the internal and external consultations. These reports were recently brought to the TPD Management Committee and will soon be presented to BGTD's Management Committee for approval to posting them on our both website.

Action: Post report on website.

Status: The reports have been sent to translation and will be posted shortly.

4. Bilateral Meeting Program

Bilateral Meeting Program with stakeholder groups is part of TPD's transparency initiative. An evaluation of this program was conducted in the summer of 2004. TPD is implementing an action plan to address weaknesses identified by the evaluation and enhance the BMP with the objective of greater value-added interactions. GPIM is pleased with this initiative and commended TPD for its commitment and effort to improve the BMP.

Action: TPD will go back to Associations in June for feedback on BMP.

5. Timeliness of Drug Review

Jenifer Collette, Advisor, OBT, gave an update on backlog reduction. TPD previously made a commitment to reduce the backlog by 90% between March 31, 2003 and March 31, 2005. That commitment has been met. Another commitment has been made through the Therapeutic Access Strategy (TAS) to have the 90% of reviews completed within the posted performance targets by March 31, 2006. TPD is well-positioned to meet this new goal as the workload has decreased considerably now that the backlog has been eliminated. As part of the TPD Project Management initiative, each NDS/SNDS/ANDS/SANDS submission is assigned a project manager. Jenifer briefly explained the role of the project manager and stated that one of the main goals is to ensure that submissions are of the highest possible quality when they come in the door. Sponsors are encouraged to contact the relevant RPM to arrange pre-submission meetings or to obtain regulatory guidance. Other initiatives, such as the Good Guidance Practices Initiative, should also help ensure the quality of incoming submissions. Now that the backlog has been eliminated, TPD expects to achieve internationally competitive performance through "review-in-time".

6. Upgrading Requirements for Antiseptics for Professional Use

Dr. Thea C. Mueller led the discussion on the decision to upgrade requirements for antiseptics for professional uses.

NDED met with members of GPIM on April 25, 2005, to discuss the issue. NDED agrees that the current method of evaluation of antiseptic products that are used in Canadian institution such as hospitals, nursing homes, etc does not adequately establish the safety and effectiveness of these products. It was agreed that guidelines specifying test methodology and efficacy criteria are necessary. Such guidelines would not only ensure that Canadian products are evaluated by the same standards utilized by other regulatory agencies, but also address the serious public health issue of infection control. NDED's draft guidelines were sent to Dr. Richard Marchand (GPIM) for comment to determine whether they reflect the type of guidance industry is seeking.

GPIM received the draft guidelines from Dr. Mueller and will be providing comments by next week. If the document becomes an official document, it will take longer to implement as it will require a more extensive consultation.

Action: GPIM to provide comments by next week (May 27).

9. Dispute Resolution Committee

Erin McAlpine, Project Officer, Office of Business Transformation, TPD referred to the Agenda Item Summary. A copy of the Notice was distributed. The Draft Guidance Document: *Reconsideration of Final Decisions Issued for Human Drug Submissions* was released by Health Canada and posted for consultation on the TPD and BGTD websites on February 22, 2005. Also posted for comment were the two Issue Analysis Summaries describing the analysis supporting the draft guidance document, and proposals for related changes to six Health Canada guidances and policies. The consultation period ended on April 29, 2005, but the comment period has been extended. GPIM committed to provide comments within the next 10 days.

Action: GPIM to provide comments by June 6.

Status: Comments were received on May 28, 2005.

10. Adjournment: Meeting adjourned at 3:05 p.m.

11. Next Meeting: November 16th, 2005, in Montreal
Next meeting will likely be in French.

Mr. Omer Boudreau
Director General
Therapeutic Products Directorate