

GRUPEMENT PROVINCIAL DE L'INDUSTRIE DU MÉDICAMENT (GPIM)  
and the  
THERAPEUTIC PRODUCTS DIRECTORATE (TPD)  
Therapeutic Products Directorate - Boardroom 2048  
Holland Cross, Tower B, 2<sup>nd</sup> Floor

Wednesday, May 26, 2004 - 1:00 p.m.

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Participants:

TPD

Omer Boudreau, Associate DG  
Ellen Birnbaum, OBT  
Bruce Erickson, BPS  
Laura Freeman, OBT  
Gail Gervais, Liaison Unit, OBT  
Micheline Ho, SMAB  
Fern Levine, BOS  
Denise Quesnel, Liaison Unit, OBT  
Mary Raphael, Policy Bureau

GPIM

Pierre Morin, DG, GPIM, Co-Chair  
Grégoire Hovington, Solumed

Regrets:

James Bellis, Inspectorate  
Carole Bouchard, HECS  
France Dansereau, Inspectorate

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1. Opening Remarks

Omer Boudreau bids everyone welcome and proceeds with introduction of participants. After presentations, Omer Boudreau mentions that some of the OBT team members have been asked to address the Good Guidance and Good Review Practices Initiatives which has been added to the agenda. In addition, he indicates that copies of the latest issue of TPD News will be of considerable interest to GPIM for it relates the success achieved in reducing the backlog in processing NDS and ANDS submissions. The 50 percent reduction goal has been exceeded.

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A second publication is also circulated, titled "Moving Forward: Health Canada's Therapeutics Access Strategy which relates progress on Health Products and Food Branch Initiatives.

Pierre Morin expresses pleasure at participating again in these bilateral exchanges that have demonstrated considerable value over the years. Exceptional circumstances have reduced the usual contingent representing GPIM but the agenda was built on issues submitted by members.

Pierre Morin acknowledges that considerable progress has been achieved in reduction of some backlogs but that DINs have not seen similar progress and there is still much to do with processing NCs within default and without conflicting with DINs.

2. Approval of the Agenda

The Agenda is approved as drafted.

3. Approval of the November 12, 2003 Meeting Notes

Pierre Morin states GPIM's agreement with the contents of the Meeting Notes. He adds that on the issue of the Quality Initiatives he had wanted to stress not only the use of a vocabulary that was similar to that used in Industry but the meaning was also the same and he had felt it should be emphasised.

4. Targeted Substances and Guidelines

Items 4.1 and 4.2 are part of the same issue. 4.1 states the requirements outlined in the Guideline while 4.2 raised the issue of its application when the DIN holder outsourced its manufacture and distribution to a third party. In this instance, does the DIN holder need a controlled drug substance? If so, does he still need a security cage and a (QPIC) Qualified Person in Charge? Or should these two requirements lay only with the company that does the outsourcing that should also hold a controlled drug substance licence?

Unfortunately, no one from the Office of Controlled Substances could attend the meeting but a briefing note was prepared and conveyed to GPIM. The note does not quite dispel the confusion in interpreting the Guidelines.

GPIM was also given a contact name, Mr. Darren Horne, Manager, Licences and Permits Division, Office of Controlled Substances, Drug Strategy and Controlled Substances Programme, Healthy Environments and Consumer Safety Branch should he require additional information regarding licencing requirements.

5. Good Guidance Practices and Good Review Practices

Laura Freeman (project lead for Good Guidance Practices) made a presentation on updating both Good Guidance Practices and Good Review Practices projects; Caroline Vanneste (project manager for Good Review Practices) was unable to attend but sent her regrets.

Good Guidance Practices relate to documents published by TPD/BGTD and intended to provide regulatory, scientific and/or administrative guidance to staff and stakeholders and that need to be developed consistently, in accordance with domestic or adopted international guidelines and, for existing documents, may need to be updated respecting the two previous qualities.

The objectives are to improve the timeliness of reviews by increasing the quality of sponsors' submissions and supporting a more efficient, predictable and transparent review process. It should also decrease disputes resulting from decisions made in the absence of appropriately developed and communicated guidance.

Good Review Practices are review standards designed to ensure the timeliness, predictability, consistency, and high quality of reviews and review reports. The Good Review Practices Project is the "umbrella project"; review standards and related initiatives are sub-projects under the umbrella

Input from industry is actively sought on the proposed GGP framework, on topics for guidance development and on identifying guidance needing revision. GRP is seeking industry input into sub-projects. It is proposed to establish a Planning Committee for GGP/GRP consultations with one representative from each of the major industry associations to assist in planning external consultations for both Projects.

Pierre Morin expresses GPIM's full agreement with both projects as well as the process. He adds the comment that a third project, Good Submission Practices, could be developed from the other two as an industry initiative to complete the process.

GPIM will participate actively, with enthusiasm to both projects.

6. Future of DINs

Since the last meeting, GPIM has looked at alternatives to the replacement of DINs by ANDS.

Should the issue really be as stated that there is a considerable lack of basic product information (formulation and ingredients, active and inactive) on marketed DINs, particularly those granted before September 1994?

A solution might be requiring holders to submit both a list of ingredients and copy of a label with the next renewal of "right to sell" application.

BPS states that this suggestion is very much in line with what the Directorate is about to propose. It needs to verify whether the Minister has the legal authority to require the additional information. Pierre Morin suggests industry would gladly co-operate, given the alternative.

7. Quality Submissions

The issue has been fully dealt with at item 5.

8. Generic explanation letter of Establishment Licences

GPIM member companies are still encountering difficulties with both foreign clients and their regulators in explaining that the detention of an Establishment Licence in Canada means the holder satisfies Canadian requirements as to current Good Manufacturing Practices and has recently been successfully inspected. Therefore, the very existence of the EL issued in the name of the Canadian firm should satisfy foreign clients as well as their regulators. When the potential exporter and licence holder tries to explain this, it seems very self-serving and generally insufficient.

GPIM has been asking for some considerable time that an official generic letter be issued by the Inspectorate explaining to foreign clients and regulators the purpose of the EL and why, when it is in effect, there is no need for Canadian exporters to supply copies of inspections reports. Mr. Omer Boudreau had informed that there is no letter available because a decision was made to issue these certificates using the new CPP database when ready for manufacturing sites rather than for products.

To that effect, France Dansereau, Inspectorate, suggested that the same line related to compliance of the establishment appears on the CoC related to Compliance to GMP be added to the new CPP database.

GPIM would like to verify that there now is such a letter issued and in circulation.

9. Transition from TPD to NHPD

GPIM inquires as to whether TPD will remind DIN holders that their products (where it applies) is more appropriately an NHP and will need to be redirected to NHPD by 2009.

The Annual Notification process is underway in SIPD. NHPD has been asked to prepare a reminder notice to be included in SIPD's mailing.

10. Next Meeting

Wednesday, November 17, 2004 at 1:00 p.m. - Holland Cross, Tower B, 2nd Floor, Boardroom 2048.

Original signed by Brigitte Zirger for

Mr. Omer Boudreau  
Associate Director General  
Therapeutic Products Directorate