



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

**Wednesday, April 23, 2003 - 1:30 p.m**

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Participants:

TPD

Omer Boudreau, ADG, Chair  
Jenifer Collette, SIPD, BOS  
Gary Condran, BPS  
Michelle Crozier, PB  
Brenda Czich, PB  
Gail Gervais, Liaison Unit, PB  
Micheline Ho, SMAB  
Joyce Pon, BPS  
Denise Quesnel, Liaison Unit, PB  
Stéphane Taillefer, Inspectorate

GPIM

Suzanne Levesque, GPIM President  
Linda Dumont, Entreprises Solumed Inc.  
Jeanette Echenberg, Pharmascience  
Madeleine Fall, Laboratoires Omega Inc.  
Leonor Ferreira, Sabex 2002 Inc.  
Marco Hamel, Omega  
Pierre Morin, GPIM  
Marie-Christine Régis, Pharnalab Inc

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**1. Opening Remarks**

Omer Boudreau introduced himself and expressed regrets on behalf of Dr. Robert Peterson. Omer Boudreau is on Senior Management Training Program and replaced Lynn Bernard who has been posted to another Department. He assured GPIM that he practiced active listening and that issues will be addressed with a view to find satisfactory solutions.

Suzanne Levesque bids him welcome on behalf of GPIM and indicates the commitment of the organisation to bring forward solutions to issues that may confront us collectively.

She rapidly gave an overview of GPIM, its mission and membership.

Omer Boudreau added that the recent Budget has earmarked additional funds to support the prescription of the Speech of the Throne on improving timelines for therapeutic product review.

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**2. Approval of the Agenda**

The Agenda is approved as drafted.

**3. Approval of the September 9, 2002 Meeting Notes**

Meeting Notes approved.

**4. Update of the New Drug List**

GPIM has posted this issue over the last two or three meetings. The list has not been updated since 1999. There have been additions but very few deletions from the list. Some drugs have been on the list for forty years and the major difficulty is identifying the justification for being added to the list and for remaining on it for a duration that seems to exceed the initial need. Joyce Pon informed GPIM that a working group has been revisiting the New Drug List in a program that carried an 18 month timeline for conclusion by early 2004 - however, it is likely TPD will conclude by December 2003. There should be a updated list of additions only which will be circulated internally during Summer 2003.

**5. When will DSTS be made available to industry ?**

In short, in about two months. Jenifer Collette stated the pilot project was complete in December 2002 and it raised security issues. Re-programming is underway and the testing has been completed. At this time, the system is undergoing the QA phase of testing.

**6. When may we expect a revised DIN guideline?**

The guideline is currently in development stage. Gary Condran stated that a draft guideline will be discussed on June 25, 2003 at an open half day workshop sponsored by NDMAC to be held in Toronto. Suzanne Levesque stated that GPIM is interested in holding a similar workshop in Montreal later in the year and received concurrence from Omer Boudreau and Gary Condran. The contact person with whom to follow up is Joyce Pon. GPIM was advised that, as was done with NDMAC, the sponsoring association would be responsible for covering all expenses incurred relating to the workshop.

**7. Particular difficulties with DIN presentations for injectables**

It was agreed that the stated difficulties could best be resolved in another forum. It appeared that the concern related more to DIN Submissions, rather than injectable products.

**8. Prior written agreements with TPD not respected on submission**

These situations will be avoided once the proposed approach of designating a submission coordinator to act as a team leader is in place. The coordinator will see to it that prior agreements are respected and be responsible for keeping the submission on path in every phase of review and resolving issues as they arise. Major issues are to be taken to the Directorate level for a decision.

**9. New requirements relative to supporting data should be communicated before a review is undertaken and not discovered by Clarifaxes.**

The problem was acknowledged. Gary Condran built on the opening comments of Omer Boudreau: the government has made a commitment to reduce drug approval times and, it took a few months to get a financial commitment which was in the last Budget. It is not just a question of spending more money on the same tasks. There is a considerable effort to look and adopt different ways of doing business. Among them, the FDA model is examined closely for its

- a) project management approach
- b) pre-submission meetings
- c) keeping industry informed and in touch with new requirements

A discussion ensues and approaches suggested such as e-mail notification of changes in requirements to an opt-in mailing list but more broadly on increased use of technological tools to establish information flows with industry and other interested parties. These are being closely evaluated.

**10. Could Certificates of Suitability to the European Pharmacopoeia (CEP) be accepted in lieu of Canadian DMFs as added value to mutual recognition?**

At this time, the Canadian system does not accept the CEP which are issued by European Pharmacopoeia. However, according to Gary Condran, TPD is actively exploring the feasibility of accepting the CEP.

There is a planned visit by TPD officials to CPMP. Gary Condran advised that the three DMF formats that are currently accepted include: Canadian DMFs, European DMFs or ICH CTD formatted DMFs (provided the Open and Closed portions of the DMFs are submitted).

#### **11. Update on export certificates and establishment licences**

1) Mr. Morin thought that no Certificate of a Pharmaceutical Product (WHO Export Certificate) was issued for products with no DIN, but he was pleased that the Inspectorate was issuing them when it had the necessary evidence (and the Inspectorate will continue to do so).

2) Mr. Morin reiterated his initial request from several months ago that the Inspectorate issue a separate letter stating that a firm with an establishment licence must comply with GMPs. After the meeting, the Inspectorate changed the covering letter sent out with establishment licences to say that the issuance of an establishment licence implies that the firm is in compliance with GMPs. This was submitted to Mr. Morin, who seemed satisfied with the solution.

#### **12. Next Meeting**

The next meeting is scheduled for Wednesday, November 12, 2003 at 1:30 p.m.  
Some agenda items listed below:

Patent Register - Not all patents are listed  
Change in manufacturing site for A/DIN

Original signed by

Omer Boudreau  
Associate Director General  
Therapeutic Products Directorate