



MINUTES

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

Monday, September 9, 2002 - 1:30 p.m.

Participants:

TPD

Lynn Bernard, ADG, Chair
Louis Boulay, VDD
Michelle Crozier, PB
Laura Freeman, SIPD-BOS
Gail Gervais, Liaison Unit, PB
Taras Gedz, BPS
Mary Hill, SMAB
Medic Ndayishimiye, Inspectorate
Denise Quesnel, Liaison Unit, PB
Mary Raphael, PB

GPIM

Suzanne Lévesque, Présidente du GPIM et V.-P.
Assurance qualité et Affaires réglementaires chez Sabex

Pierre Morin, GPIM
Linda Dumont, Solumed
Jeanette Echenberg, Vice présidente, Affaires
réglementaires, Pharmascience
Leonor Ferreira, Sabex
Jean-Paul Lefebvre, Riva
Marie-Christine Régis, Fréga

1. Opening Remarks

Lynn Bernard welcomed GPIM participants, expressed regrets on behalf of Dr Robert Peterson and, with the help of distributed organisation charts reviewed and explained changes that have taken place within the Health Products and Food Branch since our last meeting as well as those that have occurred within the Therapeutic Products Directorate over the same period.

Within the Branch, organizational changes aim at creating specialized directorates to develop the specific knowledge base and efficient regulatory skills for the ever evolving sectors that come under the Branch's responsibility.

The recently created Marketed Health Products Directorate is charged more with execution data analysis tasks; policies on issues such as pharmacovigilance will continue to be developed at TPD, in consultation with the MHPD.

The organizational changes that have taken place within TPD should yield greater efficiencies. GPIM expressed concern at seeing so many bureau directors in an acting capacity. Lynn Bernard assured participants that confirmations should be forthcoming shortly.

2. Approval of the Agenda

Two items are added to Other Issues: the first seeks to identify the right person within TPD with whom to follow-up on an issue raised at a previous meeting, and the second, to follow up on such an issue. These changes having been noted, the Agenda was approved.

3. Approval of the December 20, 2001 Meeting Notes

The December 20, 2001 Meeting Notes were approved as written.

4. Review of Drug Submission Performance Report (Annual & Semestrial)

Three specific issues related to the Performance Reports are proposed by GPIM:

a) the overall volume of business seems to have stabilised to within ± 10 percent; there does not appear to be much growth to be anticipated over the coming years.

b) two areas of activity still account for most of the backlogs: screening and chemistry and manufacturing. The problem seems to lie with time to pick-up;

c) the use of the same resources charged with the review of DIN applications and the review of Notifiable Changes creates a real conflict of interests; the fact there are fees for DINs and a default date for NCs exacerbate the issue.

Lynn Bernard agreed the volume of business seems to have reached a plateau and feels there is little to be gained by increasing resources to reduce backlogs without developing ways to prevent future backlogs. No comments were sought or made on the progress in staffing based on approvals obtained more than a year ago.

Screeners have been merged with reviewers and the results are positive and improvements should show in upcoming performance reports.

There is agreement on the apparent conflict of interest resulting from having the same resources used to process DIN applications and Notifiable Changes. A comprehensive guideline to industry on Notifiable Changes is in preparation and should be circulated shortly.

Action: TPD - Comprehensive guideline to industry on NC's is in preparation and should be circulated shortly.

5. Issues carried over from previous meeting: December 20, 2001

5.1 New Drugs - Old Drugs

A cross-Directorate working group is currently focussing on the priority issues surrounding a new drug in relation to its definition in Part C, Division 8 of the Food And Drug Regulations, and to the various policies and guidance documents referencing 'new drug', including the New Drugs List. The New Drugs List is a key component of this policy review initiative. We are striving for a 12-18 month timeline.

Action: TPD will examine administrative and management criteria, deliver recommendations and see to implementation within 12-18 months.

5.2 DIN Guidelines

A draft guideline should be available for consultation early in 2003.

Action: TPD - Draft guideline, available early in 2003.

5.3 Establishment Licence - An explanatory document to explain its importance. Countries where GPIM members export either have not heard that Establishment Licences constitute the primary evidence that a Canadian Licence holder proceeds in compliance with cGMP or have chosen not to believe the Canadian Licence holder whom is still required to produce the latest inspection report, including comments that may not be relevant to the transaction. Initially, faced with this situation, GPIM had sought a formal statement on "Government Letterhead" stating that Canadian law required of those with manufacturing, distribution or import activities to be Establishment Licence holders and that the issuance of said licence was conditional on a satisfactory inspection report confirming compliance with GMPs.

Failing this, GPIM sought to have the narrative portion of the inspection report separated from comments so that the first could be made available. This latter request did not seem feasible.

GPIM members have difficulties to convince their customers in foreign countries that the Establishment Licence is a sufficient evidence of GMP compliance. They want the Inspectorate to supply a letter indicating that a firm is GMP compliant to licence holders that require such a letter for export purposes. Medic Ndayishimiye from the Inspectorate Directorate will submit the request to the Inspectorate Management.

Action: Inspectorate - To provide a response to this request.

5.4 Updating the electronic transmission of information issue -eCTD

Louis Boulay has, for many years, been involved in TPD and Canada's participation to ICH's M2 working party. ICH Steering Committee is meeting as of this day until September 12 in Washington D.C. and should adopt the final version of the eCTD (M4). It will then be proposed for implementation in Canada.

6. Update on the Status of the Changes to Marketed Drugs Policy

There has already been reference to a comprehensive guideline to industry on Notifiable Changes. GPIM notes that the management of changes to marketed drugs is a burden and that there might exist simpler ways to achieve the same purpose namely, as an example, having licence holders report a series of predetermined changes on product licence renewal for instance.

7. Dissolution Testing - An Unwarranted Requirement

The issue arises in specific circumstances involving a change of manufacturing site for some products. Taras Gedz states that a dissolution profile is a minimal requirement. From a regulatory perspective a new bio-study could be appropriate to ensure that the

product manufactured at the new site is within the same parameters as that manufactured at the previous site. In certain situations, comparative dissolution profiles could be sufficient to support the change.

8. Other Issues

8.1 DSTS Update

Laura Freeman informed attendees that a pilot project involving some 15 to 25 sponsors (there were more than 60 volunteers) will get underway within 3 or 4 weeks. The participants should cover the broad spectrum of small to very large sponsors. GPIM queries as to whether some of its members are participating; the information is not immediately available but will be followed up in the next few days.

8.2 Follow-up on an issue of new drug determination.

An issue was raised at the May 30, 2001 meeting that a drug was marketed in Canada without any authority to sell or as a device and that the FDA consider this drug as having a new drug status. Some of the people then with TPD have moved on and GPIM is informed Joyce Pon at BPS is the person to be contacted.

8.3 Conformity to product monograph and labelling standards.

On May 30th, 2001, Dorothy Walker had noted that there is a considerable number of submitted marketed Category IV and Labelling Standard products that do not conform to the signed attestation by the sponsors. GPIM inquired about what corrective measures may have been put in place and whether there continues to be a quality of application issue.

Action: The Policy Bureau and the Senior Medical Advisory Bureau will verify this point and report back.

9. Closing Comments and Next Meeting

Suzanne Lévesque regrets the absence of Dr Peterson and suggests that at least one of the Bureau leaders or directors attend TPD-GPIM Meetings so that we may become better acquainted with one another. Lynn Bernard states her intention to follow-up on this suggestion.

Action: Bureau Leaders or Directors of TPD attend GPIM meetings.

Next Meeting

April 23, 2003 at 1:30 p.m.

Original signed by

Lynn Bernard
Associate Director General
Therapeutic Products Directorate