

**Meeting Notes from the
consultation meeting between**

**GROUPEMENT PROVINCIAL DE L'INDUSTRIE DU MÉDICAMENT (GPIM)
and the
THERAPEUTIC PRODUCTS PROGRAMME (TPP)**

Therapeutic Products Programme Boardroom (2048)
Holland Cross, Tower B, 2nd Floor

Friday, December 15th, 2000 - 2:00 p.m.

Participants:

TPP

Robert Peterson, Chair
Danièle Dionne, BCE
Laura Freeman, SID
Sultan Ghani, BPA
Micheline Ho, BPA
Jean Lambert, BCE (by phone link)
Denise Quesnel, Liaison Unit, OSPCCQ
Lisette Richard-Carrière, Liaison Unit, OSPCCQ
Lucie Rondeau, BCE
Mike Ward, IPD

GPIM

Suzanne Lévesque, GPIM, President (Sabex)
Raymond Baribeau, (Confab)
Jeannette Echenberg, PharmaScience
Leonor Ferreira, (Sabex)
Angelina Habimana, (Omega)
Jean Lessard, (Van Waters & Rogers)
J.P. Lefebvre, (Riva)
Julia Lipszyc, (E-Z-EM Canada)
Pierre Morin (GPIM)
Clinton Walker, (Van Waters & Rogers)

1. Opening Remarks

Robert Peterson welcomed everyone to this first formal TPP/GPIM meeting under his tenure. Presentation of participants. Pierre Morin introduced Suzanne Lévesque and wished Dr. Peterson well in his new responsibilities and offered GPIM's cooperation whenever it can be beneficial to both TPP and members. Suzanne Lévesque presented GPIM and some of the new directions into which she has plans to lead it.

1.1 Export Certificates

This was the first formal opportunity to thank TPP management for agreeing to reduce fees for export certificates and GPIM members are most pleased with the results.

1.2 Organisational Issues

Robert Peterson informed GPIM participants that he was originally hired as an Associate Director General in a mainly scientific capacity. Since assuming the Director General responsibilities, a strong manager will be hired to fill the vacant Associate Director General position. He also informed participants that additional funding and some two hundred new openings have been approved for TPP. However, staffing has not progressed as rapidly as hoped.

2. Performance Against Standards for DIN Applications

The latest Quarterly Drug Submission Performance Report (to the end of September 2000) showed a significant deterioration of the backlog situation both for screening and review of DINA Applications over the last year. Average backlog went from a little over 10 percent of workload over the previous three quarters to more than 50 percent. In reviews, GPIM noted that workload has been decreasing while backlog has been increasing. The situation needs to be corrected.

TPP has been addressing the issue but relief is still some time away. As mentioned earlier, additional positions have been opened but have not yet been staffed. That process in itself is slow. A considerable effort to reduce backlogs in DINA Applications had met with success until the last quarter. There will be further attempts to repeat this!

2.1 Guidance document

GPIM inquired about the means to improve the quality of applications and submissions. Essentially, it is of considerable interest to both to minimize the incidence of second screening and second review of an application or submission.

TPP concurred and reported that by minimizing these incidences, TPP could concentrate more resources on first screenings and reviews thus reducing delays. A guidance document is about ready to go out to industry for DIN Applications with a template for this purpose. A workshop could be held as early as March.

2.2 Pre-September 1994 Non Notified DINs for the Export Market

Following the disposal of non-notified pre-1994 DINs some two years ago, (where these were to be used exclusively for export trade unless willing to submit a full information package - essentially a new submission), GPIM had been [20(1)(b)(c)]

TPP stated not only did it not intend to proceed with such a process, but that it wanted to [21(1)(b)]

GPIM to TPP's proposed policy. [20(1)(b)(c)]. Members have always indicated that such products are not on the Canadian market but where manufactured in compliance with cGMP.

It was agreed that GPIM would prepare and present a document raising the issues involved and addressing TPP's concerns.

ACTION: GPIM

3. Update on International Harmonization

A telephone link was established with Jean Lambert in Montreal who informed GPIM that three Mutual Recognition Agreements (MRA) have been signed so far. One is in place with Switzerland where the confidence building period has successfully been completed and where it was in process of implementation (a harmonized batch certificate was in place). A MRA has also been signed with Iceland, Liechtenstein and Norway this past summer and was currently in the confidence building period .

The Europe-Canada MRA's confidence building period has been extended to January 2001. One of the EC members did not meet the MRA's requirements, hence the delays in the context where the EC has decided to proceed with all members or none. An issue was a specific GMP sector for which corrective measures were requested. The strategic position of the EC could change under pressure from its members' industries. An harmonized batch certificate common to all countries with a MRA in place should soon be available. Discussions were underway with [21(1)(b)(c)] that could lead to a Memorandum of Mutual Recognition (MMR) in a relatively short period of time.

However, pharmaceutical company integration into an increasingly important market could bring about changes. In the meantime, work was underway to develop a Memorandum of Understanding (MOU) with [21(1)(b)(c)], particularly with GMPs.

MOUs were expected to be in place shortly with [21(1)(b)(c)] on the exchange and acceptance of inspection reports.

3.1 ICH

The November meeting in San Diego saw the sign off of a finalized guidance on the Common Technical Document (CTD), together with a pan-ICH implementation plan that calls for the acceptance of CTD-based submissions in the three ICH regions by July 2001. Canadian implementation plans are progressing well. Despite the continuing existence of some region-specific information, the CTD is expected to reduce the time and resources needed to compile submissions for the various regulatory authorities. Further efficiencies will be achieved with the introduction of the eCTD, the specifications for which should be completed by the end of the year. Regional documents will be available in XML later this year.

3.2 Harmonized GMPs

It was agreed we were moving closer and closer to harmonized GMPs and the section concerning sterile products was also almost finished. Early in the new year, there should be a draft circulated for industry comments (including sterile products) which could lead to the adoption of the 2002 edition of Good Manufacturing Practices (Harmonized) to be in place before the end of 2001.

3.3 Drug Master Files (Testing and Approval of Active Raw Materials)

GPIM raised again the need of doing things differently such as maybe approving Drug Master Files of bulk active ingredients from which dosage form manufacturers could draw in reference, thus reducing time lines for important portions of screening and review.

TPP informed GPIM that an internal working group has been assigned to look into the DMF issue.

4. Establishment Licensing - Documentation

4.1 Inspection Reports

GPIM inquired as to whether the narrative could be separated from the ratings. The current format poses confidentiality problems, particularly when reports are circulated to third parties that have no need for the narrative portion of the report. Danièle Dionne agreed to assess the system and indicated that recommendations should be formulated in time for our next meeting.

ACTION: Danièle Dionne

4.2 Validation Waivers

Many members recalled there being a mention of validation waivers that could be granted under special circumstances; requests have been forwarded but no response has been forthcoming. Sultan Ghani stated that at no time was there question of waivers being granted, and that while concurrent validation is accepted for small batches destined to small markets, three (3) batches are still required, eventually.

4.3 Labels and Export Certificates

GPIM sought clarification on information received that TPP is now requiring labelling information in both official languages with applications for export certificates. GPIM was under the impression that labels in the language of the importing country was more relevant.

TPP reported that the requirements is real and that bilingual labels are to be supplied with export certificate application for a product. Unresolved was the issue of labels for products not sold on the Canadian market.

5. Dates for Meetings in 2001

May 30th, 2001 - 1:00 p.m.

December 20th, 2001 - 1:00 p.m.

Original signed by

Robert G. Peterson, M.D. PhD. MPH
Director General
Therapeutic Products Directorate

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