



Notes from the consultation meeting
between

le Groupement provincial de l'industrie du médicament
and the
Therapeutic Products Directorate
TPD Boardroom, 2048 Holland Cross, Tower "B"

May 30, 2001 at 1 p. m.

In attendance:

TPD

Lynn Bernard, Associate DG, Chair

David Clapin, BPA

Laura Freeman, SIPD, BPC

Patricia Garand, OMS

Gail Gervais, Liaison Unit, OSPCCQ

Denise Quesnel, Liaison Unit, OSPCCQ

Stéphane Taillefer, HPFB Inspectorate

Baerbel Traynor, OMS

Dorothy Walker, BPA

GPIM

Suzanne Levesque, GPIM President and
V.P. Regulatory Affairs and Quality Assurance,
SABEX Inc.

Raymond Baribeau, Director, Business
Development, CONFAB Laboratories

Angelina Habimana, Director, Regulatory
Affairs, OMEGA Labs

Jean-Paul Lefebvre, Director, regulatory
Affairs and Quality Assurance, Laboratoires
RIVA Inc.

Marc Patry, President, Entreprises SOLUMED
Inc.

Pierre Morin, Director general, GPIM

1. Opening Remarks

Lynn Bernard welcomed everyone and explained her new functions in the realigned TPD. She indicated that she had held a number of positions within many government departments, including Privy Council and that she is now responsible for ensuring non-scientific management functions within TPD function optimally.

She explained the most recent re-organisation changes which resulted in the formation of two new Directorates in the Branch and she included the mission each is expected to fulfill.

Suzanne Levesque welcomed Lynn Bernard. She mentioned that most of the issues raised in these consultative meetings are in fact management and organisational issues and that scientific issues are seldom raised. Participants then introduced themselves.

2. Approval of the Agenda

The agenda was approved with updates made to the participant list.

3. Approval of the December 15, 2000 meeting notes

It was agreed that Pierre Morin would confirm by early next week the approval of both the French and the English December 15, 2000 meeting notes. He reported that the latest versions had only recently been tabled and that he had not yet had a chance to review them.

4. Outline Cost-Recovery

Patricia Garand reported on the cost recovery revision process which was the basis of the Phase IV cost-recovery initiative. Her presentation concluded with results of a study carried out by KPGM. Members were informed that an action plan was being drafted and that it should be posted on the TPD web site within a month. In addition, external consultations would be expected come the Fall. GPIM asked if the Steering Committee could be given the opportunity of reviewing the action plan first given the fact that the Phase IV initiative affected all interested parties and stakeholders. The suggestion was noted. An exchange took place on whether some of the internal constraints had to do with TPD's financial practices and there was acknowledgement that changes will require regulatory action.

5. Pre September 1994 DINs

Pierre Morin tabled a document on behalf of GPIM which outlined the current legal requirements here in Canada and practices in some European countries. In Belgium and France there was evidence tabled that these countries would assist their local exporters by granting them "for export only" marketing authorisations, that are equivalent to a DIN. The document then concluded that the practice of using non notified DINs (pre or post September 1994) for export purposes should continue. GPIM also felt that current policy should be changed and that pre September 1994 non notified DINs for which all that is required is attestation that the product conforms to a labelling standard or to a Category IV product monograph could be notified with no other procedure than appending the attestation to the notification form.

TPD will follow up on GPIM's response. Dorothy Walker noted that there are a considerable number of marketed Category IV and labelling standard products that do not conform to the attestation signed by the sponsors.

ACTION: Dorothy Walker and David Clapin agreed to look at the document, consult with the Bureau of Policy and Coordination, and report back to GPIM by September 2001.

6. Delays in submission processing and presentations

GPIM members voiced their concern and frustration over TPDs delays in processing submissions and its presentations.

GPIM noted that according to them, the latest quarterly performance figures show the situation has gone from bad to worse, creating conditions that can have direct effect on small businesses where production planning and scheduling are critical activities.

GPIM recognised that the process moves along very nicely once a submission is picked up by a screener or reviewer, however noted, Stakeholders are still waiting to receive a copy of the DIN guidance document. TPD agreed to make screening guidelines available to industry for comments. There should also be an update on marketed products.

GPIM indicated that they would gladly forego their proposal to waive a portion of the applicable fees on presentations and submissions that have exceeded performance standards by 50 percent or more if replaced by a simplified approval process for low risk products, or a default mechanism for product approval. Following a discussion between David Clapin and Suzanne Levesque, GPIM agreed to formulate proposals along these lines.

As part of that same discussion, Pierre Morin asked Lynn Bernard if the possibility of outsourcing services with either university faculties or private contractors had been fully explored. The response was that at this time it had not been felt necessary to explore these avenues. Pierre Morin also inquired as to whether a succession plan was in place within TPD to ensure the directorate does not become paralysed through the absence or loss of a key employee. TPD responded that a succession plan is not yet in place.

ACTION: GPIM to submit proposals to TPD by the end of September.
TPD to provide an update on marketed products and the DIN guidance document.

7. Policies are not applied in a standard and even manner

A GPIM member outlined what requirements his products had to meet in order to be approved by TPD. Even after informing the Inspectorate of the issues, competing products were being marketed as devices or with no market approval at all. Stéphane Taillefer agreed to take the details of the problem and reported that it would be looked into further. Continued discussions

included that some of these products were considered new drugs in the US and that the member supported the FDA's position.

GPIM agreed to supply BPA, David Clapin or Dorothy Walker, with data supporting the position that these products should be new drugs.

ACTION: GPIM to write directly to Mr. Jean Lambert, HPFB Inspectorate with their complaints so that the Inspectorate can act on them.

GPIM to supply supporting data to BPA.

Dennis Brodie, BPC should be invited to the next GPIM/TPD meeting to discuss policies.

8. Review of Decisions

At a previous meeting, GPIM had asked that the notation and narrative portions of inspection reports be separated so that those being supplied with notations would not get the narrative portion of the report which often raises questions that are of no concern to the reader. Danièle Dionne of the HPFB Inspectorate was to come back and report on this item. Stéphane Taillefer indicated that it does not appear possible to split the two and that the question was somewhat moot since all that a company is required to produce is a copy of its establishment licence. GPIM contended that while that may be the legal position, real world clients still ask for a copy of the inspection report (which can be requested from Access To Information, ATI) and that it would simply make life easier all around if the notation portion of the report could be easily detached.

ACTION: HPFB Inspectorate will look further into the issue.

9. Next Meeting

Thursday, December 20, 2001 at 1:00 p.m. is agreeable to all.

Original signed by Lynn Bernard for

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

Canada