

Meeting Notes
Between
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, November 17, 2004 - 1:30 p.m.

Attendees

TPD

Omer Boudreau, Associate DG, Chair
Ellen Birnbaum, OBT
Michèle Chadwick, BGTD
Gail Gervais, Liaison Unit, OBT
Micheline Ho, SMAB
Mary Raphael, Policy Bureau
Denise Quesnel, Liaison Unit, OBT
Heather Throop, ADMO
Baerbel Traynor, BOS
Michael Wood, BOS

GPIM

Pierre Morin, DG, GPIM, Co-Chair
Leonor Ferreira (Sabex)
Madeleine Fall (Omega)
Linda Dumont (Solumed)
Marco Hamel (Omega)

1. Opening Remarks

Omer Boudreau bids welcome to attendees and mentions Item 6. has been removed from the Agenda since BGTD cannot attend this meeting, therefore update was sent to GPIM 16/11/04.) "Biogenerics : How is the issue being approached, what are the key questions for regulators and how can we participate in the process?"

Pierre Morin apologises for late arrival of his group. He states that GPIM has noted marked improvements in performance and that TPD's Quality Agenda is starting to reflect on relationships between TPD and members' staff. GPIM members' perceptions of TPD evolution are generally upbeat.

2. Approval of the Agenda

Omer Boudreau mentions remaining agenda items and Pierre Morin states agreement with the contents.

3. Approval of the May 26, 2004 Meeting Notes

The Notes have been distributed and meet with GPIM's approval.

4. The Rationale for old/new Drug Determination

Background:

Back in April 2003 it was expected the Revision of the New Drug List would be completed by year end. Where are we at?

Outcome Expected:

A revised list and a better understanding of the criteria for inclusions.

Mary Raphael explains that there is a group of projects in progress: among the issues is the question as to whether the old drug/new drug approach is consistent with the way Health Canada does business currently. Also being evaluated are the issues of Division 8 and of sufficient time. The outcome should be well drafted policies instead of just a revised List. Consultations with stakeholders should take place this coming Spring. GPIM agrees with the process but hopes it comes rapidly to a conclusion because of the resource wasted in the current process.

5. Public Announcement of DIN Issuance

Background:

- a) Currently only NOCs are announced publicly when issued. What is the rationale for not making similar announcement for DINs?
- b) Releasing the date of submission at the same time as issuance of NOCs and DINs would help industry benchmark its quality submission performance.

Outcome Expected:

Improving public information and allow industry to improve quality submission performances

Michael Wood informs GPIM of the proposed coming on line early December of a new NOC database (based on the DSTS) that will contain much more information on each product than is currently available.

Launch is awaiting resolution of some issues such as discrepancy in product monographs. The Canadian reference page has been removed from the accessible information.

It will be timely, after the database launch, to explore the possibility of including DINs.

6. **Performance**

Background:

Review of performance and of the various consultative activities concluded and still underway.

GPIM is proposing to lump comments on performance reports as well as on the consultative activities that were carried out since the last bilateral meeting: on bilaterals, on financial models, on Good Guidance and Good Review Practices and others.

Outcome Expected: Good feedback

GPIM has noted considerable progress in eliminating the backlog on a wide range of submissions and hopes targets will be met by March 2005. Over the past year, it has participated in numerous consultations from defining financial models (a process that GPIM noted was well done); summary basis of decision; the future of bilaterals; annual notification; public participation in the consultative process and look alike, sound alike drug names. Each and every one of these participations resulted in constructive suggestions for improvements and warranted the time and effort invested on the part of participants. Organizers are to be commended.

GPIM hopes the progress noted in processing DINA submissions(screening and review) will be sustained even if the number of submissions increases to average levels.

GPIM is particularly appreciative of the project management approach.

Ellen Birnbaum on behalf of Laura Freeman and Caroline Vanneste updated participants on the Good Guidance Practices and Good Review Practices Initiatives. A consultation process was launched last August and posted on TPD's web site as well as information documents to assist in exploring the issues involved in the project.

A complete review of existing guidelines is currently underway and a manual for guidance drafting is in preparation.

7. **Look Alike/Sound Alike Initiative**

Michèle Chadwick speaks to draft guidances in a presentation aimed at implementing a strategy to minimize risks associated with look-alike sound-alike health products.

The strategy will provide a framework for Health Canada to review drug names; it will be implemented in phases and drug name will become piece and parcel of the overall pre-market review process with a specific timeline of 90 days on the name issue.

Sponsors will be able to consult database of names that should be avoided and are to include in their submissions a proposed proprietary name and two prioritized alternate name choices.

Comments are welcome up to November 26 next.

8. Next Meeting

Wednesday, May 18, 2005 from 1:30 to 3:30 p.m. - Holland Cross

Original signed by

Mr. Omer Boudreau
Director General
Therapeutic Products Directorate