



Meeting Notes

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

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

In attendance:

TPD

Dr. Robert Peterson, DG, TPD, Chair
Dennis Brodie, BPC
Lisa Burke, BPA
Michele Chadwick, BPA
France Dansereau, Inspectorate
Laura Freeman, SIPD-BPC
Pauline Gaudry, BPC
Gail Gervais, Liaison Unit, BPC
Medic Ndayishimiye, Inspectorate
Denise Quesnel, Liaison Unit, BPC
Brigitte Zirger, BPA

GPIM

François Angers - Omega
Raymond Baribeau -
Linda Dumont - Solumed
Leonor Ferreira - Sabex
Jean-Paul Lefebvre - Riva
Pierre Morin, Director General, GPIM

1. Opening remarks

Dr. Peterson extended a welcome and greetings to everyone. The changes that ~~h~~ occurred at the former TPP, i.e. the emergence of three distinct directorates has created a need for considerable reorganization if for no other reason than establishing new lines of co-operation. In fact, this realignment of services requires that each of the directorates define its mission and organization plan to meet its objectives. Also involved are staffing and locale issues. It also affords the opportunity to streamline and add to the efficiency of the Bureaux such as BPA resulting in better assessments and shorter timelines.

2. Approval of the Agenda

The agenda was approved after adding a new item on PIC/S and MRAs.

3. Approval of the May 30, 2001 meeting notes
Pierre Morin indicated GPIM's agreement with the contents of the May 30, 2001 meeting notes.
4. Separating the narrative from the ratings in inspection reports
Due diligence is not limited to a copy of the license. By this sentence, GPIM members indicated that some of the parties they are dealing with are not yet satisfied with being given the establishment licence number when they used to get a copy of the ratings of the inspection report. France Dansereau indicated it is not possible to separate the narrative from the ratings portion of the inspection report. However, the Inspectorate is quite willing to look into this to see how to best accommodate this request.

ACTION: Inspectorate - To look into this and be rediscussed at the next meeting.

The EL mentions:

"this licence is issued in accordance with the Food and Drugs Act & Regulations (Division 1A & 2) for the following activities and categories of drugs."

The date of the last inspection is also indicated on the EL"

5. The use of pre-September 1994 non-notified DINs for export purposes
Dr. Peterson informed members that following review of the information tabled at the last meeting by GPIM, the Directorate still believes that should a sponsor intend to use a nonnotified pre-September 1994 DIN for export purposes, a full information package should first be submitted for review so as not to create confusion in the minds of importers.

Pierre Morin pointed out members using those DINs for export voluntarily submit their production to cGMPs and inspection. In addition, the proposed procedure and policy is a roundabout way of withdrawing DINs from the market without the process associated with such a measure. GPIM suggested there could be a voluntary recall of non notified DINs which would go some way in determining the number and nature of outstanding valid non notified DINs. TPD will consider this suggestion and make a determination.

ACTION: TPD to consider suggestion and make a determination.

6. A new DIN Application Guideline - announced but..
Michele Chadwick indicated that it is important that a guideline be consistent with regulations. A workshop will be organized to help develop guidelines, share problems at this end. GPIM has asked Sultan Ghani's group to put on this workshop of 1 day or 1 ½ day. TPD will sit down with a submission committee to develop Guidance Documents.

ACTION: TPD

7. Means to improve timeline performances: bundling screeners with reviewers
GPIM pointed to the considerable improvement in assessment and review performances. GPIM suggested screeners should be “bundled” with reviewers in the various bureaux. Dr. Peterson agreed and indicated that the suggestion is already being implemented.
8. Update the New Drug List and to remove what should not be listed
The New Drug List may have been reviewed as recently as 1999 but Leonor Ferreira, for GPIM, reviewed examples of drugs that are listed :
- Benzalkonium chloride/ boric acid - according to list not only is the drug product a new drug so are the drug substances
 - Drug compositions containing butalbital - are considered New Drugs (drug product and drug substances) - is it not a labelling issue because of potential drug abuse - would it not be better to have labelling standards issued forcing all manufacturers of these products to update labelling consistent with TPD requirements for these products
 - Aminocaproic acid;
 - Other potential abuse products requiring labelling standard instead of new drug status - Diazepam, methadone, oxycodone, papaverine
 - Dimethyl sulfoxide - considered new drug substance and new drug product according to the list
 - Products that have been on Canadian market for a very long time -Dipyridimole, Hyaluronidase, streptokinase, sodium nitroprusside
 - Combination products of old drug substances that are new drugs for the same indications as the individual, i.e. antibacterial and anti-inflammatory combination product of old drug substances whose indications are not new
9. Information dissemination from the Directorates: a policy?
In a letter sent to the Canadian market (hospitals) a DIN holder quotes a senior Inspectorate Officer as stating that one of our members is not authorized to market a given product. The officer claims not to have said the contents of the statement but we have seen no action to correct the information. Our member's reputation in the market suffers. A copy of the letter is shown to Dr. Peterson and to France Dansereau. The Inspectorate will investigate further. Copy of the letter given to France Dansereau.

ACTION: Inspectorate to investigate

10. Electronic transmission of information: a new timeline?
Dr. Peterson addresses GPIM's concerns about APETI by stating that it remains just as useful as ever. What has changed is that some of the resources that were very scarce as recently as earlier this year have become available and eager. The Directorate has decided the time and conditions were ripe for outsourcing. Panel will be convened again to evaluate the results. The results should be worth the wait.
11. Policies and /or guidelines come into force without having been published
Not specific to oral contraceptives. Pierre Morin was informed by a member that he was told his product was Schedule F but there was as yet nothing to indicate TPD's intention to include that product in an Amended Schedule. Dr. Peterson mentions that a problem, since corrected had developed with some oral contraceptives. The situation has since been corrected.
12. PIC/S and MRAs
Pierre Morin relates the delays and frustrations of a member attempting to enter one of the EU countries. Information available indicates that exchanges that should have taken place in the PIC/S framework had not and that a new inspection of the manufacturing facilities had to take place.
- France Dansereau explains the role of PIC/S as a Convention for Pharmaceutical Inspection, essentially providing for the exchange of information such as inspection reports, unlike MRAs which accept participants inspection reports as their own.
- As yet, an MRA has been concluded with Switzerland, with members of EEA -EFTA and with the European Community. Only the agreement with Switzerland is currently in place. Part of the confusion may have come from a May 2000 document on supplementary guidance which infers a greater role for PIC/S.
13. Next meeting
May 22, 2002 - 1:30 p.m. Agreed.

Original signed by

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