

GRUPEMENT 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 12, 2003 - 1:30 p.m

Participants:

TPD

Omer Boudreau, Associate DG, Chair
Anne Bowes, OPML
Micheline Ho, SMAB
Fern Levine, SIPD, BOS
Lisa Maille, OPML
Arvin Naperstkov, BPS
Denise Quesnel, Liaison Unit, OBT

GPIM

Pierre Morin, GPIM, Co-Chair
Leonor Ferreira, Sabex
Jean-Paul Lefebvre, Riva
Veronica Werner, Paladin
Madeleine Fall, Omega
Marco Hamel, Omega

1. Opening Remarks

Omer Boudreau bids everyone welcome and apologises for having to leave the meeting early. Micheline Ho will co-chair after his departure. Pierre Morin informs TPD that Suzanne Levesque, President, GPIM could not be here because of a long standing commitment scheduled in Washington.

Pierre Morin states GPIM's pleasure in witnessing implementation of TPD's Quality Management Initiative. Part of the enthusiasm is in anticipating the outcomes and another part appreciates that the vocabulary and its meaning are the same as those in use universally. An additional source of satisfaction is the current review of performance reporting that may see the introduction of qualitative information.

New DIN Guidelines Joint Workshop : The recent joint workshop on the new DIN Guidelines held October 2nd in Montreal was very successful and opens opportunities for more events of this nature.

2. Approval of the Agenda

Agenda is approved.

3. Approval of the April 23, 2003 Meeting Notes

Pierre Morin states GPIM's agreement with the Meeting Notes as drafted.

4. Carried over issues:

4.1 Patent Register - Not all patents are listed

GPIM had expressed concern with the fact that not all patents were listed on the Patent Register and had made suggestions it be patterned similarly to that of the United States. Anne Bowes agrees that not all patents are on the List and reminds participants that its scope is limited : listing is not an obligation and the rules as to what should be listed are drawn by Industry Canada. Currently, the List is made up of patents containing a claim to the medicine (which includes formulations) or use of the medicine.

4.2 Change in manufacturing site for A/DIN

Currently, a DIN owner need not notify TPD for a change in manufacturing site. However, the TPD form required for a change in manufacturer's name for a DIN requires that a box be checked stating, no other changes to the DIN product has occurred or is planned; otherwise the product may need to be reviewed again. To avoid this regulatory burden, the DIN owner should change the manufacturing site before or after having notified TPD of the change in manufacturer's name. Arvin Naperstkov agrees with the description of the situation and does not foresee any regulatory changes in the near future.

4.3 New Drug List: the rationale for inclusion of drugs

GPIM is trying to get a clear understanding of the rationale for inclusion and maintenance of drugs on the New Drug List, particularly for drugs that have been on the market for many years.

Essentially, the inclusion and maintenance of a product on the List is a function of assessed risk and also linked with another oddity: DINs. A recent event, the request by the minister to be informed of all drug products containing bovine content or derivatives concluded on the impossibility of TPD to adequately meet the request and suggests avenues for further action such as a review of old drugs or even abolishing DINs altogether which would also resolve the issue of the New Drug List.

5. Performance

The last available performance report indicates that there appears to be considerable problems with evaluating C & M data both at screening and review levels for NDS, ANDS and DinA's. What solutions are being put into place and when? The treatment of Notifiable Changes seems also to be suffering delays, are there remedies afoot?

According to Omer Boudreau, the situation has greatly improved over the last few months as a result of TPD's sustained focus on backlog reduction. TPD News in its September / October 2003 issue states that by December 31 next the overall backlog for new drug submissions should have been reduced by 34 percent (excluding notifiable changes). Very recent figures for C & M data review indicates that backlogs have significantly improved. As for remedies, a combination of the project management initiative, the additional funding provided by the last Budget and continued focus on the issue should see rapid improvements over the next few months.

6. Coordination with NHPD- What happens after January 1st, 2004

What happens after January 1st, 2004 for the review of vitamins and minerals and other products currently reviewed by TPD?

The recent (October 31, 2003) information note issued by TPD on the issue covered both DIN submissions already in queue and those wishing to obtain market authorization to the satisfaction of GPIM.

7. Product Monograph

The use of the new Product Monograph Guidance document is said to be voluntary at this time but members are encouraged to implement it during the review process.

Sponsors are not required to follow the template for the Consumer Information Section (Part 3) if the current package insert covers all aspects of the Consumer Information Section. Labelling of reference and generic products should be consistent.

Since October 1, 2003 the product monograph may be submitted, on a voluntary basis, using the new Product Monograph Guidance Document and Templates as part of an NDS, an SNDS or a Notifiable Change. This is Phase One of the implementation process which may include a case by case consideration for submissions waiting in queue for review. But even then, it remains on a voluntary basis until October 1, 2004.

8. Next Meeting

GPIM agrees with the proposed date of Wednesday, May 26, 2004 - 1:00 to 3:00 p.m. - Holland Cross, Tower B, 2nd Floor, Boardroom 2048

Original signed by

Mr. Omer Boudreau
Associate Director General
Therapeutic Products Directorate