Health Canada Santé Canada

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MEETING NOTES
THERAPEUTIC PRODUCTS PROGRAMME
ADVISORY COMMITTEE ON MANAGEMENT

TPP Boardroom
Holland Cross, Tower B, 1600 Scott Street
Ottawa, Ontario
January 17- 18, 2001

Members:	Jim Blackburn (Chair) Luis Barreto Andrea Baumann John Blatherwick Robert Goyer Ruby Grymonpre Mitchell Levine Stuart MacLeod Kenneth Michalko Brenda Nunns-Shoemaker John Parks Jack Rosentreter Bonnie Salsman John Stewart Pamela Zabel	**Secretariat:**	Robert Peterson Marion Law Denise Quesnel Carolin Vaughn
		Presenters:	Marta Caris Ross Duncan Sultan Ghani Geoff Middleton Brigitte Zirger
Regrets:	Malcolm Seath Beverley Townsend	**Observers:**	Barbara Benning Dennis Brodie Danièle Dionne Julia Hill Jean Peart

1. Opening Remarks *(J. Blackburn)*

Dr. Blackburn welcomed everyone, thanked the new members for agreeing to serve on the Committee and the previous members for their continued support. A roundtable of introductions followed.

Dr. Peterson indicated that the TPP has finalised the operational planning for 2000-2001. This will involve a review of many aspects of the Programme including the need to discuss the role of ACM with respect to the two new Directorates. TPP proposed topics that would require a new kind of support and involvement as the realignment activities move forward. There are some international and domestic challenges that will need to be addressed (legislative renewal is one example). It is clear that the role of external bodies is necessary to support the work of the new realignment Programmes. This being accomplished, the focus is to move ahead with realignment.

2. Review of the August 24th Meeting Notes *(J. Blackburn)*

The meeting notes of August 2000 were approved as presented.

3. ACM Membership *(J. Blackburn)*

Three new members have joined the ACM:

Dr. Mitchell Levine, Director, Centre for Evaluation of Medicines, St. Joseph's Hospital, Hamilton, Ontario, as a nominee from the Canadian Medical Association;

Dr. Kenneth Michalko, Senior Director, Regulatory Affairs, Novopharm, Stouffville, Ontario (and Teva Marion Partners Canada, Montreal, Quebec), as a nominee of the Canadian Drug Manufacturers Association;

Mr. Jack Rosentreter, Director, Pharmaceutical Consulting Group, Manitoba Health, Winnipeg, Manitoba, as a nominee of the Pharmaceutical Issues Committee (PIC).

4. TPP's financial situation as we move towards realignment *(G. Middleton)*

G. Middleton presented the 2000-2001 budget, and the operational planning challenges that the TPP is facing with the realignment. Cash management, realignment, targeted funding and cost recovery were identified as issues impacting resources/funding. The cost recovery shortfall is forecast to be $4.4 M. This is an ongoing problem relating primarily to changes made to the Medical Devices. It is hoped to work towards resolving this issue during the coming fiscal year.

TPP's financial situation as we move towards realignment *(continued)*

For the benefit of new members, Dr. Peterson explained the complex process of revenue collection through cost recovery and budget distribution, and appropriations for the operational plan of the current fiscal year.

He indicated that without having to contend and shift resources to address unexpected policy activities of previous years (i.e. medicinal marijuana, industrial hemp), it has been easier this year to prepare a more accurate operational plan. The operational planning exercise for the new fiscal year will be challenging as the TPP moves to operate as two new Directorates.

Some members expressed concerns with regards to the TPP financial situation. Overall TPP is in a good position with a planned expenditure budget of $74 M (approx.) against our anticipated budget of $71.6M. And there may be a surplus at the end of the fiscal year, but realignment would be responsible for that surplus. Any surplus during the fiscal year will be considered for activities in support of the realignment process. Staffing is also a priority and TPP is moving forward to meet new regulatory obligations.

5. Realignment of Health Canada *(R. Peterson)*

The TPP will continue to operate as one Programme until the end of this fiscal year (March 31st). Although aspects of the restructure are beginning to be put in place, the split into two Directorates (Therapeutic Products Directorate (TPD), and Biologic and Genetic Therapies (BGT) should be final by April 1, 2001. The new Branch, Health Products and Food, has four principal directorates (Food, Office of Natural Health Products, Biologic and Genetic Therapies, and Therapeutic Products) with support from other Branch and offices. Some current TPP functions (e.g. compliance and enforcement) may include more details of how the Programme will move to serve the entire Health Products and Food Branch. The Realignment action plan will consider other common activities and determine if it is appropriate to have this capacity within each directorate shared between Directorates or located at the Branch level. Post-marketing activities is also another function which will be similarly considered. The approach is to look at the challenges, and find a structure that would achieve results without duplicating the resources and finances.

Status: Realignment has made it clear that the TPP will no longer pursue Agency status. Dr. Peterson confirmed his intention to stay with the TPP, and is actively looking to recruit a new Director General for BGT. He is currently Acting Director General for BGT. ACM members indicated that they would be willing to take an active part in decision making.

Process: A two day **Management Retreat** was held in November 2000, to discuss operational planning and the plan for the Realignment of the TPP. An **Extended Management Retreat** was held in January, 2001 (2 days/125 middle managers). This Retreat focused on information sharing and helped with direction on the realignment challenges, the proposed models and their varying implications, and priorities. A transition team will be appointed.

Realignment of Health Canada *(continued)*
There are currently 930 positions in the TPP, 300 of which are not filled. A full Human Resources review is expected.

Additional changes: There is a departmental initiative to strengthen the regional functions. TPP already has regionalisation within the current Bureau of Compliance and Enforcement (BCE). The Branch will look at areas where functions/activities can be carried out in the Region as well as Ottawa and also consider functions which may be more successfully relocated to the Regions.

Mr. Ian Green is the newly appointed Deputy Minister. Mr. Green had strong support and the confidence of his predecessor Mr. David Dodge.

6. Presentation on the *new* Branch structure
Diane Gorman, Assistant Deputy Minister of Health Products and Food Branch

Ms. Gorman described the new organizational chart, presented some of the challenges, and was then available for questions. She mentioned that at the two day Strategic Planning Retreat, the challenges that were identified are common across the Branch. She reported that the new Deputy Minister supports the current realignment concept, and she does not foresee any significant changes to the mandate and structure proposed in the Re-alignment document.

Some of the principles for Realignment in the Branch are:

- Manageable span of responsibilities (eg. creation of BGT);
  - evolving importance of biologic and genetic therapies
- Risk management - strong horizontal issues management;
  - continuum of risk for products for the purpose of maintaining and improving health;
- Branch functions to provide support and co-ordination;
- Policy and Strategic Planning - to provide Branch framework and tools;
- Strong regional capacity.

Challenges:
Knowledge capacity: The Branch must continue to build a knowledge capacity to continued to forge more partnerships and create international opportunities

Increase in demands of new technologies: The Branch must strive to become a leading edge capacity and must be more innovative with partnerships.

Biotechnology: There is a great potential to increase the health of Canadians, and we have to work to gain the public's trust.

Presentation on the *new* Branch structure / Challenges *(continued)*
Office of Consumers Affairs and Public Involvement (OCAPI) : There is an increased demand for public information. We have to be proactive in risk communication to give freedom of informed choice.

Legislative renewal: It is the Branch's intention to put this back on the political agenda. If this is successful, the next stage is consultation.

Budget: 90% of the Branch's budget goes on staffing. There is a need to look at targeted funding and how this impacts on the budgetting process. In addition, we need to start focussing on establishing Health Canada as a workplace of choice and to increase our commitment to staff to encourage a healthy work/life balance.

Training was raised as a key factor to success. There is no University course on government business, so we must invest and build capacity by training for the longterm. Ms. Gorman recognized that training was already being done on risk management.

Ms. Gorman discussed the role of the new Chief Scientist, Dr. Kevin Keough. He will be an advisor to the Deputy Minister on science issues. It is unlikely that he will deal with operational (science) issues. Dr. Keough will be starting at Health Canada on April 1, 2001.

7. Discussion on TPP's Human Resource Strategy for the next year *(B. Zirger)*

B. Zirger reported on the progress since the August 2000 meeting. The Human Resources Initiative (HRI) team and working groups are in place, the recruitment initiatives have started, and the marketing efforts are also well underway. An informal count shows that close to 100 vacancies have been filled since July 2000. This is a very soft number that highlights the need for a proper tracking system - a priority for the next few months. The Recruitment Working Groups for the Medical Officers are working on a special advertisement (for MOF positions) that will be published in a number of journals between February 1 to 10, and mailed to all physicians in the National Capital Region in mid-February.

The ACM members indicated concerns about the staffing process. They feel that it is too cumbersome and lengthy and people may be lost in the process to other positions.

The TPP has participated in job fairs (Post Secondary Recruitment in the fall 2000) and are planning to attend the following:

- PSC's EE job fair - February 7th
- Canadian Federation on Biological Societies - June 2001

ACM members offered comments on how the MOF poster could be changed to be more effective. While the version for the journals had been frozen, members comments were reflected in the poster being mailed to physicians in mid-February.

They are developing marketing materials and are proud of their MOF Poster that will be published in February.

8. Update on Activities:

. **Advisory Panel on the Product Licensing Review Process** *(R. Goyer)*
R. Goyer expressed the expectations and frustrations of this Panel. Its role is to look at the recommendations from the HIV Working group which include issues such as timeliness, transparency and post- marketing surveillance. The Panel would like to be more than an advisory panel and contribute more to the decision-making. It is not clear to them, if this is their mandate. The next meeting is scheduled to April 23 and 24, 2001, in Ottawa.

. **Public Advisory Committee (PAC)** *(M. Law)*
This Group may evolve into a Branch public advisory group. To consider this further, TPP will work with the PAC working group and the Branch (OCAPI). An individual with credibility should lead PAC. The Office of Consumer Affairs and Public Involvement (OCAPI) was established to coordinate and support the public involvement activities for the Branch. The TPP is anxious to support this initiative. The ACM agreed this is a worthwhile project.

. **Public Consultation on Xenotransplantation** *(A. Mills / M. Law)*
Due to time constraints, the slide presentation was distributed and Marion Law gave a brief update. Health Canada has funded the Canadian Public Health Association (CPHA) to conduct consultations on xenotransplantation across Canada. The consultations (in 5 regions, Vancouver, Yellowknife, Saskatoon, Halifax, Toronto and Quebec City) are set to begin as early as March 2001, and are expected to be completed by the end of July 2001. The report from CPHA is expected in November 2001.

. **Clinical Trial Reform** *(D. Brodie)*
The proposed amendments to Clinical Trial regulations are on hold due to a lack of consensus. Research Ethics Boards for one remain concerned about the shortened time period. Consumers are generally not supportive of the proposals.

The Industry has proposed a 7 day default in response to the Programme's proposal to 2 day (48 hour) target time. Generally, Industry does not support administrative targets. Their position is that the Programme often does not meet established target time. TPP is waiting for further direction from the Minister's Office.

ACM agreed to express their concerns to the Minister and invite him to come to the next meeting and address these issues.

Update on Chemistry and Manufacturing Review - Backlog and proposed solutions
(Marta Caris / Sultan Ghani)

Sultan Ghani presented the action plan to address the backlog of submissions. Four review Units have been put in place to manage the different submissions types. TPP is working with the manufacturers to improve the quality of the submissions and working to maintain the consistency and quality of the reviews. With the recent staffing of new reviewers, it is expected that the backlog will be cleared in 3 to 6 months. The issue of contracting out was brought to the table. Due to conflict of interest, the fact that chemistry and manufacturing submissions contain protected manufacturing information, contracting this activity is difficult. In some circumstances, retired TPP employees are sometimes hired on contract to review submissions.

The consistent use of the clarifax was a problem, but this is now resolved. This will ensure reviewers are keeping current with new science in this area. A training programme is in place for new staff and a refresher course, designed for existing staff has also been established.

Guidance Documents: Guidance for Industry Preparation of Drug Identification Number Submission (DINs/Quality Chemistry and Manufacturing) Information, Review Template Quality Overall Summary (Drug Identification Number Submission). The draft is now ready and should be available by beginning of February. The backlog of submissions in Chemistry and Manufacturing is an important issue and the ACM members indicated that they would like another report at the next meeting. They want to fully understand the situation in order to participate with finding a solution.

9. Institute on Risk Management *(A. Baumann)*

Andrea Baumann raised the issue regarding the need to create and gather support for the establishment of an Institute to cover research and risk management issues. A number of Institutes have been established and successfully contribute to these areas.

Andrea proposed that the ACM could initiate discussions around establishing Institute to address risk management issues. The first step could be a letter to the Chief Scientist.

ACTION: *Institute to contact the Chief Scientist*

10. Product Monograph *(R. Duncan)*

Ross Duncan (TPP) presented an update on the Product Monograph (PM). He reviewed the outcomes of the consultation in September and next steps from this consultation. The Programme is currently revising the PM guidelines to reflect the new format. At the same time the Programme will be exploring the issues of ownership and dissemination of this document. ACM asked to be kept informed.

Product Monograph *(continued)*

Some issues raised by the ACM for consideration when moving this project ahead include:

- importance of establishing ownership
- balancing the information to ensure it meets the needs of consumers but does not prevent them using the medication (e.g. unclear information about adverse effects)
- timeliness of providing this information to consumers

12. Use of External Advisory Panels for Operational Issues and Managing Conflict of Interest *(R. Peterson)*

TPP is considering extending the use of Expert Panels to reviewing parts of drug submissions and participating in the decisions on pre-market approval and post market issues. It was noted that Health Canada does not use expert panels to the same exert as other comparable regulatory agencies. The successful use of external expert panels depends on the approval of management of potential conflict of interest. As the ACM is an external body, Dr. Peterson asked this group to consider this issue and work with the TPP to strengthen the process in place to allow us to develop closer working relationships with external expert panels. In conclusion, there was general agreement to the concept. TPP will do an issue analysis and this will be discussed at the next ACM meeting.

ACTION: *TPP to prepare issue analysis*

13. Discussion on Article: *Tales from the Other Drug Wars* *(R. Peterson)*

Dr. Peterson introduced the document. TPP will be preparing an analysis of this document. ACM is invited to provide comments to the Director General on their opinions and reactions to the article. The source is credible so the issue should be addressed. It was suggested that ACM should confine comments to matters concerning the TPP. Other related similar materials were published in L.A. Times and Globe and Mail.

ACTION: *ACM members to provide comments to TPP.*

14. Meeting Evaluation and Closing

Again the members appreciated having fewer formal presentations on the agenda. It allowed for more in-depth discussions on the different issues with the presenters. It was suggested that following the meeting, the minutes style with record of decisions was appropriate, but the members would receive a report, providing a summary of discussions on a number of issues that the committee will be pursuing in more depth. Also, the members would like to receive the agenda in a

timely fashion before the formal meeting so that they can provide valuable input at the meeting, and would also like to be kept abreast of issues as they develop.

As an orientation tool for new members, and also to assist the ongoing members, it was also suggested to create a binder containing information such as general guidelines, organizational chart, list of acronyms, major policy documents and the latest quarterly report. The TPP will begin preparing this information to provide to members at the next meeting.

At the next meeting, ACM will be serving 2 Directorates (Therapeutic Products Programme and Biologics and Genetic Therapies).

Future Agenda Items:

- Mandate of ACM (within Re-alignment)
  - " How can ACM bring advice to two new directorates?
- Invitation to Deputy Minister
- Invitation to Chief Scientist: his vision, etc.
- Chemistry and Manufacturing Review Issue
- Update on Human Resources
- Post-market surveillance
- Issues specific to clinical trial Reform
- Backlog issues
- Link to other Advisory Committees to TPP
- Policy to address off-label uses: considerations and impact
- How can we use foreign reviews to assist with Canadian reviews
- Public confidence and how this impacts on how TPP does its job

Next meeting: **May 9 - 10, 2001** (10:00 a.m. start on May 9th)
TPP Boardroom, Room 2048, Holland Cross, Tower B
1600 Scott Street

Jim Blackburn
Chair