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MEETING NOTES
ADVISORY COMMITTEE ON MANAGEMENT

THERAPEUTIC PRODUCTS DIRECTORATE (TPD), BIOLOGICS AND GENETIC THERAPIES DIRECTORATE (BGTD), INSPECTORATE

TPD Boardroom
Holland Cross, Tower B, 1600 Scott Street
Ottawa, Ontario
August 22-23, 2001

Members:	Jim Blackburn (Chair)	**Secretariat:**	Robert Peterson
	Luis Barreto		
	Andrea Baumann	OSPCQ	Fern Levine
	John Blatherwick		Denise Quesnel
	Ruby Grymonpre		
	Mitchell Levine	**Presenters:**	
	Stuart MacLeod		David Clapin
	Brenda Nunns-Shoemaker		Ross Duncan
	John Parks		Brian Foster
	Bonnie Salsman		Pauline Gaudry
	David Skinner		Patricia Huston
	John Stewart		Marion Law
	Pamela Zabel		Beth Pieterson
			Karen Reynolds
			George Samiotis
Regrets:	Kenneth Michalko	**Observers:**	Dennis Brodie
	Jack Rosentreter		Vicky Hogan
	Beverley Townsend		Danièle Dionne
			Jean Saint-Pierre
			Siddika Mithani
			Margaret Stockwell
			Brian Gillespie
			Paul Roufail
			Susan Tessier
			Sue Ann Blakely

- **Opening Remarks** *(Jim Blackburn)*

  Dr. Blackburn welcomed everyone and initiated a roundtable of introductions.

  David Skinner has replaced Malcolm Seath on the Committee for this meeting.

- **Review of Agenda and the May 8-9, 2001 Meeting Notes** *(Jim Blackburn)*

  The meeting notes from May 8-9, 2001 were approved as presented.

- **Realignment - Update** *(Robert Peterson /David Clapin/Paul Roufail/George Samiotis/Marion Law)*

  Dr. Peterson updated members on the progress of re-alignment in each of the three new directorates, Biologics & Genetic Therapies Directorate, Therapeutic Products Directorate and the Inspectorate. The position of Director General, BGTD has been advertized. Interviews are expected to be soon and an appointment will be effective early in 2002. The organizational chart for the new structure of the BGTD was provided. In the TPD, **Beth Pieterson** has been appointed Director of the Medical Devices Bureau.

  Bureau of Pharmaceutical Assessment Reorganization - *(David Clapin & Paul Roufail*)

  The factors which are being taken into consideration and driving the reorganization include:

  - requirement for more coordination for the flow through of submissions.
  - difficulties in staffing the position of Bureau Director.
  - existing organization with many responsibilities.
  - special responsibilities related to Clinical Trials and the Special Access Program.
  - challenges associated with synchronizing the activities of Safety & Efficacy with Chemistry & Manufacturing.

  Three models have been developed, using the input of staff. This will be refined and further discussed at an upcoming BPA staff meeting.

  The ACM discussion, which included Directorate representation, covered the following:

- The comparison was made with the Therapeutic Goods Agency in Australia. There, the preclinical, clinical and quality groups match the Common Technical Document. It was agreed that it would be useful to be able to make use of international information available from other comparable regulators.
- Another key concern identified is that staff appear to be overloaded with work and there may not be enough managerial training opportunities. The new structure should attempt to address these issues.
- There is a need to establish the vision and clear plan for the TPD. It was pointed out that human and financial needs may differ depending on the structural model chosen. It is desirable to have the most efficient model and this would be evident eventually through performance reporting. The final model needs to allow for better communications to permit the substantial 'horizontal' coordination that will be necessary. It was suggested to examine the issues affecting performance - e.g. is the handoff between Chemistry & Manufacturing and Safety & Efficacy the biggest problem? Determine the drivers and how best to set up project teams.

  To better facilitate the coordination and integration of the review streams there could be an additional management level. The end point is to bring products to market sooner with appropriate safety and efficacy review. Safety & Quality could be aligned along with processes such as Research & Development, Manufacturing, Marketing as an overall business process to link them together. It was suggested to review the structures of the TGA, Sweden and the EMEA. It is hoped that the changes made will look minimal but will be significant in terms of impact.
- Radiopharmaceuticals may fit better within the new reorganized BPA. There are similarities between radiopharmaceuticals and small molecules.

Bureau of Licensed Product Assessment - *(George Samiotis)*

Dr. Peterson provided an overview of the current activities. The Branch intends to maximize the opportunity to improve post market surveillance of all products regulated by the Health Products & Food Branch. There is also a need to establish policies on how to engage external

groups to partner with us and take on aspects of this work e.g. collecting drug utilization effectiveness data.

In January 2000 the BLPA released a study on how to improve post market surveillance within the new realigned Branch. Various models and options were presented and reviewed. At this time, the Branch Executive Committee appears to support the centralized model but has not yet taken a final decision.

In the discussion that followed several key issues were raised and discussed, namely that the need for a Bureau Director, emphasis on finding adequate resources (human and financial), the possibility of partnering with other groups such as the Canadian Institute for Health Information, the Population & Public Health Branch (currently conducts vaccine surveillance), and provincial counterparts.

It must also be determined how to make the links from HPFB to other parts of the Department that have an interest in post market surveillance. First Ministers are pursuing issues around drug cost effectiveness and there is a link with post-market surveillance. The BLPA has established links with the FDA and the TGA. We need to have access to their information as well as sharing Canadian data.

Common Services - *(Marion Law)*

Focus groups have begun to examine how to best reconfigure the Bureau of Policy and Coordination and Common Services which includes all of the Offices currently reporting to the Director General's Office (Office of Strategic Planning, Communications & Quality, Office of Knowledge Management and the Office of Management Services.) The Office of Continuing Education is now providing services for the Branch.

The exercise of deciding which services could be shared among the three new Directorates and which need to be replicated within each Directorate is complete. The TPD must now focus on structuring these services for its own use. The model currently developed would put

all common service in 2 new Bureaux - Policy and Management Services. A final decision is expected soon.

The question arose about providing these services to Natural Health Products Directorate. NHPD does not have the resources to duplicate everything that the TPD has. There may be some potential for a self-care initiative which would look at some low risk therapeutic products (e.g. some non-prescription drugs).

It was proposed that the ACM address this to the Minister. The NHPD should have the same support services as the rest of the Branch's directorates and that this is the time to take the opportunity to set it right in light of realignment.

Inspectorate responsibilities re:NHP: Currently NHPD does not have much activity. When necessary, the TPD or Inspectorate has taken some action and special measures but currently, NHPs are exempt from most regulations. The NHP regulatory framework has not yet been approved. It was suggested the ACM note to the Minister should include past comments on NHPs by the ACM. (NB - previously there were 2 members on the ACM from the NHP community).

ACTION: **ACM to consider sending note to the Minister regarding NHPD**

4. Medical Devices Bureau Update - *Beth Pieterson*

Beth Pieterson provided an overview on the current role, responsibilities and structure of the MDB.

She also outlined some of the major accomplishments and challenges facing the Bureau including that last year the Medical Devices Bureau played a very active and influential role in the Global Harmonization Task Force and continues to work closely with the FDA and the European agencies. In 2003 the Quality Systems Requirements come into effect. There

is a concern in the industry that not every medical device manufacturer will be compliant. However, a number of manufacturers are already having two audits - one directed by the FDA and one directed by a recognized body from the EU and the TPD is hoping that the European groups will apply to receive recognition by Canada.

The Bureau faces a number of challenges including resourcing. There are proportionately significantly less medical device reviewers in the MDB than in other comparable regulatory agencies.

Another challenge is the increasing number and diversity of combination products - devices with pharmaceuticals, devices with biologics. The clarification of a product (drug or device) is often based on the historic use and treatment (therapy) of the product. When making a clarification decision, the MDB interacts with other agencies and information is often exchanged but the decision is taken within the Directorate/Branch. This is becoming more of a challenge as medical devices and drugs become more complex.

5. Pharmaceuticals Management/Product Licensing - *(Karen Reynolds & George Samiotis)*

The presentation put into context this new initiative and how it relates to Product Licensing. This initiative stems from the First Ministers' Action Plan for Health Renewal which holds Pharmaceuticals Management as one of its highest priorities. The plan identifies four key areas for collaborative work:

1. strengthening the surveillance of the therapeutic effect of drugs that are approved for sale in Canada;
2. developing strategies for assessing the cost-effectiveness of prescription drugs;
3. creation of an intergovernmental advisory process to assess drugs for inclusion in provincial drug plans; and,
4. examination of best practices for prescribing, dispensing and administering drugs.

It was indicated that under Legislative Renewal we will require new regulations that will reflect the Product Life Cycle when the new Health Act is approved. The TPD is trying to link the Pharmaceutical Management Initiative and Product Licensing to take advantage of the opportunity for funding. This will lead to more resources for policy development, drug review, post-market surveillance, etc.

In response to the request from the TPD for the ACM to provide input to this initiative, it was suggested that the Provincial level is the real site of action and that the best way to move ahead with this initiative would be by bringing in the academic centres: the 9 pharmacy schools, 16 medical schools and others. The academic centres would focus on the issues, not the politics.

A gap with respect to capacity-building was identified, e.g. as in the areas of Drug Safety, Pharmacoeconomics, etc. An HR plan is required and it was suggested to look to the Canadian Institute of Health Research (CIHR). It was also suggested to specify what type of drug products would come under this scrutiny - High risk human prescription, high cost human prescription, etc.

ACTION: Dr. Peterson - Commitment - 6 weeks from now:
Follow up with the next significant document for comment by the ACM. Following this, a teleconference may be organized.

ACTION: ACM
There was a suggestion that ACM meet with Roy Romanow (*Romanow Commission on the Future of Health Care in Canada*) to provide input to the Commission. The data gathering phase is until the 22nd of November 2001 and the report is due November 2002.
The impact of new technologies on the health care system should be pointed out. It was suggested that the ACM make a recommendation to establish a Centre of Excellence for studying the impact of new technologies on the health care system. The ACM send in a letter of intent indicating willingness/intention to make a submission to Mr. Romanow. Romanow

Commission Terms of reference were provided by Andrea Baumann. See the website: http://www.healthcarecommission.ca/

ACTION: NEXT WEEK Jim Blackburn will send out an e-mail to the ACM members requesting key points to cover in the letter and submission.

6. Product Monograph - *(Ross Duncan)*

An update on the Product Monograph (PM) project was provided. The four broad principles of this project were presented: Public Access; Use of the PM; Quality Information; and Shared Responsibility and progress to date was discussed.

The ACM members generally agree that the consumers' needs must be met and that this will take many forms with written information as well as electronic. It was suggested that there could be a partnership with existing sources which deal with patient information.
There are many reliable health websites and these should be examined and could be used as references. The expectations from this project are a functional database and a determination of the source(s) of funding to support it.

The maintenance of Product Monographs was identified as an issue, not just in terms of updating the PM but also the inclusion of new indications and the recurring issue of off-label use of the drug.

There is a concern with the limitations of the PM for clinicians. Currently the PM cannot include off-label use indications. A suggestion to partner with clinicians to ensure that patients are provided with appropriate information was encouraged. There is a view that routinely providing patients with the entire PM could be too much with the availability to interest patients.

A number of challenges were noted and discussed:

1. Ownership: The view was expressed that patient information should come from the regulator who would ensure that the content is impartial.

2. Source of funding: The PM provides a value to the health care system and an additional safety step for patient to know of ADRs, contraindications, etc. therefore, there should be support for government funding however, partnerships could be sought. The PM has been the basis of the Compendium of Pharmaceutical Specialties as well as the information put out by pharmacies.

3. Dissemination of the PM and costs involved: Electronic submissions will make things easier. The PM is available through Access to Information (ATI) but there is a high cost (both human and financial resources) to the TPD associated with this route of access. Ownership of the document is crucial for transparency and for distribution of the information. There was a question about whether or not it could be made mandatory to have the PM provided by the pharmacist.

4. Roll-out: Simple: pull up info from DPD (Drug Product Database)
   Complex: many sources of information

5. Conversion of old format to new format: The primary objective is to develop a standard template for the PM. This is an ambitious goal and it may be too ambitious to consider having manufacturers convert old PMs because it would cause difficulties to pull resources from existing activities. Therefore it may be best to develop the standard template and to start from now on.

Process: It was suggested that broad consultation be part of the objective. For the initial part of this process focus groups are being provided with a sample PM and then asked what kind of information they would want.

The focus group consultations indicate agreement on the type of content. A standard format is being developed to ensure that it is a useable product. The draft guidance document will be ready by the end of November 2001 and it will be available for comment.

Summary of the ACM Discussion and Recommendations - Ross Duncan
Partnerships with disease-oriented groups will be explored.
Functionality of the database will be ensured.
Clarity of the intent of this project will be explained
Government will pay for the PM although industry may be willing to pay something.

ACTION: Ross Duncan will provide prototypes.

7. Tabled Reports - Preparation for agenda item

Summary reports were provided in advance on Cisapride Inquest Recommendations / Action Plan, Cost Recovery, Performance Measurement Framework, the Quarterly Performance, HR Initiative, TPD All Staff Update. Time was allocated to review the tabled reports to determine which managers should be present for this agenda item scheduled for tomorrow. A request was made for someone to come from the BGTD to address the reorganization. However, there were no requests for managers for the specific tabled reports.
Additional item: request was made to include discussion of the activities of a group called 'Women in Health Protection' specifically regarding illegal Direct-to-Consumer Advertising. It was pointed out that this is where many consumer issues are raised.

8. Recap of Day 1

Reception for Robert Goyer was well-received. Congratulations to the organizers.

9. Joint Health Canada/Canadian Institutes of Health Research (CIHR) Initiative (Placebos in Clinical Trials) *(Pat Huston & Siddika Mithani)*

Pat Huston presented this topic. Regulatory policy differs from research ethics policy with respect to appropriate use of placebos in clinical trials.

The goal of this initiative is to develop a unified placebo policy for Canada that may inform future revisions to Canada's Tri-Council Policy Statement as well as constitute the basis of a Canadian addendum to the International Conference on Harmonization (ICH) guidance document ICH E-10. To do this, representatives from the major stakeholders would form a Working Committee to examine the facts, conduct public consultations, complete an ethical analysis, and develop recommendations for a unified placebo policy that would be presented at a Stakeholder's Workshop. This project should take about 18 months to complete, once funding is confirmed. The ACM was asked for comments on the proposed process for dealing with this issue and for suggestions for appropriate candidates for the Working Committee.

ACM Discussion with Clarifications from the TPD:
Placebos do have a place in assessing new treatments for conditions that are not life-threatening. Criteria are needed to determine when the use of placebos is appropriate: e.g. scientifically essential for methodological reasons, ethically acceptable. The nature of the research question must be determined; e.g. *Gingko biloba vs* Ritalin to treat ADD.

It is worthwhile to review the outcomes of the 1998 meeting for ICH E-10. The central issue there was on psychiatric studies.

If there is no distinction between the trivial risk *vs* the important risk there may be a need to ask "who is the beneficiary?" at the outset...is it the individual patient or the patient population/society as a whole. One must consider - 'is it an individual patient' or 'an individual patient *in a clinical trial'*. The goal is to minimize the risk in the active and control groups. Alternative trial designs may expose more patients to unproven treatments. There is no ideal alternative to a placebo. If a non-inferiority trial is used, the objective is to show no significant difference, which may "lower the bar" for the approval of new drugs. If an active control superiority trial is used, this could "raise the bar" for the approval of new drugs which may limit the number of drugs that have access to the market; such a policy may not pass the test of fairness to the marketplace.

Related issues, such as rescue therapy and early exit rules should be considered in the guiding principles.

Formation of the Committee: The public needs to have confidence in the method to appoint the committee members. It is hoped that 8-12 members would be adequate. It was suggested to develop criteria for membership and put out the call to an adequate number of stakeholder groups for nominees. A number of vulnerable patient groups: psychiatric, Alzheimer, frail elderly, mentally handicapped, children, etc. could be considered. A broad perspective should be considered including those who could be pro or con (polarized). The definitions of terms must be made clear as well as alternatives and how to consider them. Simulated trials, *in vitro* studies, computer models, etc. should all be considered in an effort to minimize placebo use.

It was proposed that a 2-day seminar or pre-workshop be organized to ask for interested parties and would include the key issues to set the agenda. The working group may be selected from this workshop. There could be nominees for a core group and a reserve list (working sub-group) which would be advisory members to the board.

Strong investigators on both the drug and vaccine sides are needed because they may have different perspectives. It is difficult to attract clinical trials to Canada because the infrastructure is insufficient. This may worsen if studies conducted in Canada are not acceptable to other regulatory bodies (e.g. a comparative study may be required in Canada, but only a placebo study would be acceptable to the FDA). We need to determine how we want to manage studies in Canada if they are to be acceptable. This will promote the R&D structure in Canada. For immunological and serological markers smaller populations will be used in the studies. How acceptable will that be?

Suggestion of names: David Scheffield (Halifax - Dalhousie University) and Dr. Salim Yusuf, Professor of Medicine, Clinical Epidemiology & Biostatistics and Director of Cardiology and the Population Health Research Institute at McMaster University. Also mentioned was the Fogerty Institute.

Dr. Peterson invited anyone from the ACM to become corresponding members of this issue.

Source of adequate funding is not known yet however, a precedent was set by funding the Xenotransplantation consultations, etc. and although the xeno issue affects only a small population, it has far reaching consequences.

10. Drug Investigation and Children *(Stuart MacLeod)*

As background for this topic, there was a brief review of the case of off-label use of the drug, *Cisapride*, which may have contributed to the death of a 15-year-old girl. The FDA Modernization Act (FDAMA) includes a section called the Paediatric Rule. This requires studies in children, even for old drugs. Once approved for use in children, the FDA provides the manufacturer with an additional 6-month exclusivity on the market.

The CIHR is encouraging the development of expertise in paediatric research. The champion is the Canadian Paediatric Society with support from the CIHR.

FDAMA is examining this issue and is proposing the Best Pharmaceuticals for Children Act.

The TPD has assigned Dr. Margaret Stockwell to review products approved to see if there are any paediatric indications and to examine consistency in labelling.

The Patented Medicines Prices Review Board may be the most appropriate body to look at incentives for paediatric studies.

The Canadian Regulator needs to develop a policy on this. The options are:

- to continue to 'look the other way'
- to include contraindication (this is regressive but does address RISK)
- to actively develop policy to require studies for paediatric indications

The challenge is to determine the most meaningful incentive. PMPRB could consider pricing incentives. TPD may consider fast tracking the approval process. Other incentives could include scientific tax credits.

Concern was expressed that the same argument can be made for geriatric and other vulnerable populations. The key word is 'vulnerable'.

The TPD does have a guidance document. There is also a project on the CPS and on Orphan therapeutics. Regarding ADR monitoring in children, Bruce Carleton (UBC) has met with Vicky Hogan (BLPA) about a project. He has received funding from the Bill Gates Foundation.

There was support expressed for writing a letter to the Minister of Health.

ACTION: **Stuart MacLeod** to send e-mail to members to get ideas. Vaccine side does have paediatric trials. There is a lot to learn from that.
Jim Blackburn and **Stuart MacLeod** will draft a letter.

11. Maximizing and Extending the Use of Advisory Bodies *(Brian Foster, David Clapin)*

Brian Foster provided a short presentation outlining the 7 inputs and 10 outputs in the regulatory system decision-making process specifically related to the Management of Drug Submissions Policy. The intention is to use formal expert committees for advice prior to the issuance of regulatory decisions such as Notice of Noncompliance (NON) or Notice of Compliance (NOC). Several questions were put out for discussion by the ACM: What are the priority areas for NON review? Should every NON be reviewed?
At what stage would the review be most beneficial? Is a 15-person core body large enough? Should industry expert representatives be part of the process? Should there be honoraria? The TPD would like to decrease the number of Appeals by virtue of using this process. It would improve timeliness, due process and would provide and opportunity for both sides to air their positions in view of the experts.

ACM Discussion:

There was a question about whether or not honoraria could be paid if the issue is sent out to members and there is no face-to-face meeting. Currently, teleconferences are used and the information to be discussed is sent out in advance.

There was a concern about security in the e-mail system.

Regarding Transparency: The minutes of these meetings are posted after being screened by the Proprietary & Scientific Information Assessment (Access to Information) division.

Regarding the divulging of proprietary information: By advertizing for interested stakeholders to review why a NON was provided, this indicates a submission for a specific product has been made.

The FDA Review Committees (open to Public) review i) Drug substance specific ii) specific to general area in therapy; something that can be used to develop policy, for example to set standards for approvability or nonapprovability. This second aspect - general area in therapy - would add a new dimension and may decrease the number of NONs or clarifaxes.

Medical Devices Canada (MEDEC) comments on the establishment of a cardiovascular EAC include: how to ensure timeliness when there is a 90-day target; and concerning confidentiality and Conflict of Interest.

Should the clock stop? The best we can do now is to include the information in the manufacturer's hands in our performance reporting.

Question regarding composition of an EAB - The FDA's EABs are heavily weighted with clinicians who want new products. The TPD would want other experts as well. However, this should not be a delaying tactic. There will be an evaluation set up to track this.

Transparency & Time and Conflict of Interest: The appearance of COI is difficult to resolve. One cannot operate behind closed doors. The EAB could be made optional before a NON is completed but the manufacturer would be advised that some disclosure would be necessary.

There was **general agreement** on the following:

- no Bureau representatives on the panel
- no Industry reps on the panel
- honoraria should be paid or we may not be able to attract anyone

What would trigger a NON and use of this Panel?

- if clinical data do not adequately support the indication
- if safety issue
- biologics - assembled with devices

Suggestion for topic for EAB - Should biopsies be required for 1 year following treatment with anti-cancer drugs.

What about NOC/C vs. Priority Review? It was explained that an NOC/C is usually granted when reviewers don't have sufficient confidence in the data set - but drug is promising. Priority Review is for new chemical entities, New Drug Submissions.

The chair asked if the ACM members endorse this process. They responded affirmatively. There was an invitation for anyone on the ACM to act as liaison to develop this further. No response at that time.

12. Advisory Committee on Management Objectives *(Jim Blackburn/Robert Peterson)*

Background information was provided and there was a brief overview of the establishment of the Committee. The advice provided by the members is valuable - e.g. for Clinical Trials. Natural Health Products Directorate could be invited for specific issues. The Branch needs to determine if the ACM should continue without BGTD and the Inspectorate as formal members. Dr. Peterson has suggested that each Directorate form its own ACM. The ACM members are here to represent the best interests of Canadians. Can the expectations of the original ACM still be met?

Dr. Peterson indicated that we will do further work on the mandate and invite Diane Gorman, ADM, to revisit this issue. He will continue to drive this issue at the Branch.

There was a comment that it would be costly for each Directorate to have its own ACM.

Another comment was that separate distinct units need separate advice. Each Committee should identify Branch-wide concerns. The ADM could convene semi-annual meetings with all the Chairs. **This comment was endorsed and it was suggested to expand the idea to a one-pager outlining what has taken place in the past, what could be the future role (i.e. more action-oriented committee)**.

Another comment was that the primary role is to advise the Director General and other TPD Senior Management. Then if it goes beyond - it may require additional action.

The Chair commended the staff for organizing this issue and meeting to be discussed.

Evaluation of the ACM status in December is appropriate. No further action by the ACM at this time.

13. Workplace Health *(Robert Peterson/Pauline Gaudy)*

The intent of this agenda item was for the ACM members to learn about and provide their opinion on how the TPD is proceeding with the Workplace Health Initiative in follow-up to the TPD All Staff Meeting held in June. Pauline Gaudy provided a brief presentation.

ACM Discussion:

Elaboration of the progress made so far was requested. Dr. Peterson explained that accommodations and space are priorities. The Division of Pharmaceutical Quality was relocated downtown due to lack of space at Tunney's Pasture. This problem is Branch and Departmental priority. The personal approach is being used to alleviate disruption but the effect of the move will be evaluated to find out how well it was handled and identify any problems encountered. There will be follow-up and communication of the results.

Awards: Suggestion by staff at the TPD All Staff Meeting to create the TPD Awards Suggestion Box. Criteria for the TPD Awards will be developed by the TPD Morale & Recognition Committee.

There was a positive response to the Action Plan and it is hoped that there will be follow-up. A question was raised concerning a job satisfaction survey so that improvement can be measured in the future. The recent Departmental Survey was mentioned. Ginette Workman is coordinating the Workplace Health Initiative at the Branch level. Communication is important. Progress on this initiative will be reported to staff.

Tabled Reports:

The members requested to see any significant progress on the tabled reports.

1. Cisapride: Some recommendations may be difficult to accomplish without additional resources.
2. Performance Reports: BPA performance has some improvement. BGTD performance has gone down somewhat.
3. Performance Measurement: good process
4. Human Resources Initiative: Medical Officer interviews on-going
5. Cost Recovery: Has Phase IV Report been finalized? The cost recovery steering committee is now looking to see what we can do internally re: fees, etc. and determining next steps. The CR Steering Committee - also includes Food, NHP and Veterinary Drugs Representatives. There is a need to determine how to tie in performance targets with Cost Recovery.

Phase IV for medical devices has just started. The Request for Proposal is out and the contract is anticipated to be awarded in September. Question: Is there an accepted ratio that is ideal, e.g. 50:50? Treasury Board has been asked for guidance because currently the TPD, BGTD and Inspectorate all have different ratios.

14. Meeting Evaluation:

It was remarked that the TPD listened to the comments from the last meeting. This one was much better because the topics selected were ones to which the members felt they could be of value.

The reception for Robert Goyer provided an opportunity to meet other TPD staff. One of the members mentioned that he spoke with several people and volunteered to work on some things with them.

It was suggested that the ACM may be interested in a tour of different places with the idea of moving people around within the Directorate. It would provide a good view of various staff and their work environments.

Committee members encourage TPD to consider utilizing their specific interests and expertise in ways that may assist the TPD management in specific situations.

The BPA reorganization: the 3 models do not provide a clear picture. It would be better to get the models ahead of time.

External Advisory Bodies: too much detail but it became clearer with an elucidation by Dr. Peterson.

BGTD: Some members wanted an explanation of the organization chart and to discuss other issues, as well. The Chair will follow up with Julia Hill, the Associate Director General, BGTD. Luis Barreto will discuss with her and the ADM the idea of establishing an ACM for the BGTD. However there should also still be some common ground with the TPD issues. There was a suggestion to have other ACMs meet on the same date so that a half-day could be organized to discuss common issues. It may be better to have the Chairs meet. Another option could be to have a single committee with spin-offs.

ACM *in camera* discussion

Meeting adjourned - 3:00 p.m.

15. Next meeting: December 5-6, 2001 (10:00 am start on December 5th)
TPD Boardroom, Room 2048, Holland Cross, Tower B
1600 Scott Street

Original signed by

Jim Blackburn
Chairperson