Health Canada Santé Canada

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MEETING NOTES
THERAPEUTIC PRODUCTS DIRECTORATE (TPD)
ADVISORY COMMITTEE ON MANAGEMENT (ACM)

TPD Boardroom
Holland Cross, Tower B, 1600 Scott Street
Ottawa, Ontario
December 5-6, 2001

Members:	Jim Blackburn (Chair)	Secretariat:	Andrea Francis
	Luis Barreto		Gail Gervais
	Andrea Baumann		Denise Quesnel
	John Blatherwick		
	Ruby Grymonpre	Presenters:	Robert Peterson
	Mitchell Levine		Lynn Bernard
	Kenneth Michalko		Dennis Brodie
	John Parks		Andy Butterfield
	David Skinner		Ross Duncan
	John Stewart		Pauline Gaudry
	Beverly Townsend		Pat Huston
	Pamela Zabel		Bill Leslie
			Eric Ormsby
Regrets:	Stuart MacLeod		Laura Reinhard
	Brenda Nunns Shoemaker		Marilyn Schwartz
	Jack Rosentreter		
	Bonnie Salsman	Observers:	Brian Gillespie
			Sheila Hills
			Trish Larwill
			Beth Pieterson
			Susan Robertson
			Paul Roufail
			Louise Travill
			Carolin Vaughn
			Mike Ward
			Brigitte Zirger

1. Opening Remarks (J. Blackburn)

Dr. Blackburn welcomed everyone which was followed by a roundtable of introductions.

2. Review of the August 22-23, 2001 Meeting Notes (J. Blackburn)

The meeting notes of August 2001 were accepted with the inclusion of the following amendments:

- Page 3, line 3 remove It is recognized that Canada may be too small to do this effectively;
- Page 7, line 15 remove A question arose as to how far MRAs could be taken in light of the HR shortage in Health Canada;
- Page 7, line 24 change Canadian Pharmacists to Pharmacist;
- Page 8, line 20-21 change the last sentence from There is a view that providing patients with the entire PM could be too much. to There is a view that routinely providing patients with the entire PM could be too much, however it should be made available to interested patients.

3. Management Issues

3.1 Reorganization (R. Peterson)

Office of Knowledge Management

Realignment of the Therapeutic Programme (TPP) has necessitated a review, by each directorate, of its knowledge management needs and resources. The Office of Knowledge Management has been dismantled and seconded staff have returned to their substantive positions. TPD, however, remains committed to a knowledge management strategy and to moving towards electronic filing. Several key projects, as well as ongoing system maintenance, are now being managed by the Office of Management Services, under the day-to-day supervision of a senior project manager. A second manager will be in place this month. Closer links are being established with the Departmental Chief Informatics Officer.

Status of key projects:

1. The Electronic Clinical Trial Application (E-CTA) has been put on hold because software development is behind schedule and additional hardware and staff training are required. Revised timelines will be established early in the new year.

2. Timelines for the electronic special access program (e-SAP) will also be developed early in the new year. This project is relatively close to completion.

3. It is doubtful whether work done to date on Medical Devices Class II system is salvageable. A new project plan must be developed.

4. The Advisory Panel on the Electronic Transmission of Information's (APETI) role should be reassessed given realignment, but it continues to be a valued partner in TPD's knowledge management strategy.

Environmental Assessment

The Canadian Environmental Protection Act (CEPA) was passed several years ago and came into force in September. Pharmaceutical products are subject to CEPA and an environmental assessment unit is being established in Healthy Environments and Consumer Safety (HECS).

a) Bureau of Pharmaceutical Assessment (BPA) Update (R. Peterson)

A draft reorganization model was reviewed, pending Departmental approval, it proposes to include:

- Bureau of Pharmaceutical Sciences which will encompass the Division of Pharmaceutical Quality (chemistry and manufacturing) and the Division of Biopharmaceutics Evaluation (bioequivalence review);

- Three Pharmaceutical Evaluation Bureaux which will encompass the pre-clinical and clinical functions of BPA;

- Office of Senior Medical Advisor which will encompass Clinical Trials, Special Access, Self Care, and Product Information Division.

The process to implement the new structure will be led by a Steering Committee chaired by Lynn Bernard with members from BPA as well as several other TPD Managers. An Implementation Team has been put in place to manage the implementation process. Input will continue to be obtained from staff through a working group process.

b) Bureau of Licensed Product Assessment (BLPA) Update (R. Peterson)

A decision has been taken to move BLPA to the Branch level. The new "Marketed Products Directorate" will be responsible for post-market assessment of therapeutics, biologics, food interactions with other health products, medical devices, medical incident/error, natural health products, pharmaceuticals, radio-pharmaceuticals, and veterinary health products.

c) Director General's Office (DGO)/ Bureau of Policy and Coordination Update (BPC) (L. Bernard/ D. Brodie)

The proposed new structure will allow the policy group to focus on policy issues with the operational component (submission information) becoming a division within the new Bureau of Operational Services (BOS).

BOS will incorporate the Office of Management Services, the former Office of Knowledge Management, Proprietary and Scientific Information Assessment (PSIA), and Submission and Information Policy Division (SIPD).

The Policy Bureau will be organized around skill sets and have an outward look in an effort to be proactive in approach, identifying priorities through strategic planning and environmental scanning.

d) Biologics and Genetic Therapies Directorate (BGTD) Update (L. Reinhard)

A new structure was announced in June 2001, in July implementation was initiated and priority areas were identified as:

1. Credibility and Public Trust: a draft communications approach has been written, letters have been sent to the Stakeholders keeping them informed of what is going on, three fact sheets will be finalized soon identifying who we are and what we do, and a website separate to the TPD site is being developed.

2. Generating and Sharing Knowledge: continuing existing work and increasing collaborations.

3. Risk Management and Regulatory Frameworks being developed for: blood, tissues, organs, and xenotransplantation.

4. Building Capacity: aiming to finalize the Director General position's in the new year, staffing initiatives have commenced for Directors of Research, Biologics, and Radio-pharmaceutical Evaluation.

5. People Focus: in the process of creating succession plans and management coaching, sensitivity training has been completed.

6. Building a Unified Directorate: quality system and lab accreditation review lot release system in place and assessing and modifying team review process.

4. Policy/Regulatory

4.1 Product Monograph Project Update (R. Duncan)

The purpose of this update was to: highlight the major changes in the draft revised product monograph guidance document; provide an overview of the successful consumer focus group sessions held at the end of August; and, share a provisional time line of the project's next steps.

The first draft of the revised guidance document is ready for internal consultation; issues for products such as generics, biologics, blood, vaccines, and biotherapeutics have been explored and appendices to the guidance document have been developed for bioequivalent and Schedule C and D products; national consumer focus groups were conducted with an emphasis on value, comprehension, ease of use, and readability of the proposed template for the new Information for the Consumer component (Section III) of the revised product monograph.

Highlights from the focus group research included: tremendous consistency with respect to the type of drug information that participants felt should be included; participants reacted favourably to the draft prototypes presented and routinely noted that the documents contained the same information that they themselves had identified for inclusion in this type of consumer drug information. It was clearly identified that common look and feel is very important as is the consistency of product monographs. It was also noted that physicians should be involved in distributing product monographs.

Next steps for this project are planned as follows: conduct internal followed by external consultation on the draft revised guidance document; distribute the position paper on the dissemination of PMs; initiate the pilot project to post existing PMs on the TPD/BGTD database; consult stakeholders on implementation and roll out issues.

It was suggested by the ACM members that focus groups also be conducted with pharmacists and physicians to explore how the consumer information section is structured and delivered in product monographs.

4.2 External Advisory Bodies (E. Ormsby)

The three issues tabled were: filtering to prioritize what issues go to external experts; remuneration and liability - volunteers, honoraria, contract; presentations to panel by industry, TPD, and/or special groups.

The current TPD approach regarding the above issues was discussed and consensus was reached by the committee on the following:

- it should be left to the TPD's discretion to identify what issues and at what time the advice of external expert advisory panel should be sought;

- it would be ideal to have a database as a means to access external expert resources in an expedient time frame, feasability may be an issue given the lack of experts within a given field;

- contracts may be a viable solution when third party advice is required;

- in terms of liability it is advisable to consult with legal counsel in advance to ensure all the bases are covered;

- the Food and Drug Administration may have screening criteria that may be helpful;

- when additional information is required, presentations made by industry, TPD, and/or special group would be advisable.

4.3 A Unified Placebo Policy for Canada Update (P. Huston)

There is widespread support for this initiative within Health Canada. Funding for Phase 1, the consultations before draft recommendations are made i.e. a national conference and focus groups, has been secured with contributions from Therapeutic Products Directorate, Biologics and Genetic Therapies Directorate, Natural Health Products Directorate, Office of Consumer and Public Involvement, and Canadian Institute of Health Research.

The World Health Association has reworded section 29 of the Declaration of Helsinki to read placebo clinical trails may be acceptable "Where for compelling and scientifically sound methodological reasons its use is necessary to determine the efficacy or safety of a prophylactic, diagnostic or therapeutic method, or where a prophylactic, diagnostic or therapeutic method is being investigated for a minor condition and the patients who receive placebo will not be subject to any additional risk of serious or irreversible harm."

A Working Group has been put together and nominations are still being accepted, please forward nominations to Patricia_Huston@hc-sc.gc.ca..

A National Conference is planned for March 22 and 23, 2002 in Ottawa.

Plans are being developed to create a website in order to facilitate communication, assist in the advertising of and registration for the National Conference, and to maximize public and stakeholder feedback.

4.4 Drug Investigation and Children (J. Blackburn)

The letter was sent to the Minister of Health on September 26, 2001 but no response has been received to date.

4.5 Risk Communication (B. Leslie)

A Communicating Drug Safety Information Workshop was held November 29-30, 2001. There was representation from stakeholder groups such as; consumer, medical, pharmacy, dental, nursing, and industry associations.

The purpose of the meeting was to explore issues and challenges respecting the communication of drug safety information, as well as to identify potential partnerships and associated roles and responsibilities of collaborating parties with a view to promoting safe drug use. And finally to consider options to examine the efficacy of the information delivery system.

The information presented were the preliminary results and an overview of the meeting. A more comprehensive presentation will be made at the next ACM meeting.

Common themes that emerged from the workshop:

- identify barriers that prevent conversion of information into action;
- identify factors that facilitate conversion of information into action;
- integrating pharmacist-physician interaction and safety into daily practice;
- getting tailored information to the targeted group at point of care.

In summary, the workshop was well received and a success. As well, it was clearly identified that it is time for a culture change for patients, physicians, and pharmacists, and targeted, timely and at point of care information dissemination required.

5. Tabled Reports (R. Peterson)

Dr. Peterson provided the highlights of the TPD financial status noting that next week's Budget announcement from the Finance Minister could have a significant impact on the framework of Therapeutic Products Directorate's spending.

Other tabled reports were:

5.1 Quarterly Performance Report (see item 9)
5.2 Financial Report
5.3 Cisapride Status Report
5.4 Science at Work in Center for Devices and Radiological Health
5.5 Adverse Drug Reactions in Children

6. Workplace Health

6.1 Plan to Address Workplace Health Issues (R. Peterson/ P. Gaudry)

A preliminary draft Workplace Health Action Plan for Therapeutic Products Directorate was presented. It was noted that this preliminary draft action plan has not been presented to TPD management but will be put on the January 2002 Directorate Management Committee (DMC) agenda. The plan consists of the results from staff consultations and the feedback provided at the June 20th All-Staff Meeting. The plan is themed by issue with a proposed action item noted for each.

In an effort to ensure two way communication with the staff, there will be a Lotus Notes database housing all documents related to the June 20, All-Staff Meeting. Also on this database users will be able to ask questions and provide feedback and input to issues relating to the All-Staff Meeting.

The Committee suggested it would be useful to theme the issues in the Plan by strategic themes e.g. career development identifying high priorities and what can and will be accomplished. However, there are limitations on certain objectives (e.g. accommodation) where the authority and priority setting lies outside TPD.

John Parks volunteered as a potential resource for advice on the Plan as he has extensive experience in this area.

Andrea Baumann will forward a copy of a document that could assist this group as they move forward.

7. Meeting with Science Advisory Board (J. Blackburn/ R. Peterson)

Jim Blackburn and Robert Peterson met with the Science Advisory Board (SAB) on December 5, 2001 to provide an overview of ACM activities and responsibilities and to consider potential areas of collaboration. The SAB expressed interest in several projects relating to science at TPD/BGTD.

In reviewing the membership of ACM, they commented on the lack of adequate representation from the Canadian Public and similar lack of industry representation from Quebec.

8. Cost Recovery Policy (A. Butterfield)

Cost Recovery provides approximately 50% of funding for Therapeutic Products Directorate, Biologics and Genetic Therapies Directorate, and Health Products and Food Branch Inspectorate.

Key issues raised and discussed include:

- Government of Canada switched to accrual accounting from cash accounting on April 1, 2001
- costing and revenue allocation models
- focus of current efforts is revision to existing fee regulations i.e. fee structure, new fees, addressing loopholes/ inequities
- fee mitigation and cumulative impact
- potential impact of Treasury Board Review of Cost Recovery Policy

An external consultation is planned for February or March 2002 to discuss proposed direction and issues where stakeholder input is needed, including:

- simplifying the Drug Establishment License Fees
- combining Drug Establishment License Fees and Authority to Sell Fees
- addressing cumulative impact
- timing of when evaluation fees payable

9. Quarterly Performance Report (M. Schwartz)

A review of the Bureau of Pharmaceutical Assessment (Therapeutic Products Directorate), and the former Bureau of Biologics and Radiopharmaceuticals (Biologics and Genetic Therapies Directorate) average approval time for generic drug submissions, new active substances, and priority new drug submissions were presented. It was noted that the figures are draft and will be confirmed in the final report.

10. Continuous Improvement (J. Blackburn)

10.1 Meeting Evaluation

Successes:

- it is productive to have specific questions and issues raised to the committee for advice;
- both ad hoc and formalized agenda items are mutually beneficial;
- there is adequate time to discuss issues raised.

Opportunities for Improvement:

- timely distribution of meeting notes;
- use PDF format for documents as not all members have the software to open some files e.g. Visio;
- distribute materials to Committee members earlier than a week in advance.

Forward Agenda Items:

- Draft Policy of Precautionary Principle;
- Statistics from BI and MOF (physician) Recruitment;
- Update of time lines for the Electronic Submission, Special Access Release, Medical Devices, and Website projects;
- Comprehensive presentation of the Risk Communication Workshop of November 29-30, 2001.

11. 2002 Meeting Schedule (J. Blackburn)

The proposed meeting schedule for ACM 2002 was approved as follows:

- May 8-9 (Rooms reserved at the Novotel in Ottawa)
- August 21-22
- December 4-5

12. ACM Discussion (in camera) and Closing (J. Blackburn)

Meeting adjourned at 2:00 p.m.

Jim Blackburn
ACM Chairperson