Policy Bureau Inquiries Tel: (613) 948-4623 Fax: (613) 941-1812

MEETING RECORD
THERAPEUTIC PRODUCTS DIRECTORATE (TPD)
ADVISORY COMMITTEE ON MANAGEMENT (ACM)
APRIL 9-10, 2003

ACM Members

Attending
Jim Blackburn, Chair
Luis Barreto
Andrea Baumann
John Blatherwick
Bernadette Connaughton
Ruby Grymonpre
Stuart MacLeod
Mitchell Levine
John Parks
Brenda Nunns Shoemaker
Michael Tierney
Beverley Townsend
Kevin Wilson
David Windross

Regrets
David Skinner
Jacques Turgeon

Health Canada

Presenters
Robert Peterson, Co-Chair, Director General (DG) TPD
Omer Boudreau, Associate DG TPD
Kevin Doyle, Policy Bureau (PB)
Ellen Birnbaum, PB
Joanna Copeland, PB
Bill Leslie, Marketed Health Products Directorate (MHPD)
Ian Mackay, Special Access Programme (SAP)
Ratna Bose, Medical Devices Bureau (MDB)

Observers
Chris Turner, DG MHPD
Hélène Bélanger, Bureau of Operational Services (BOS)
Jacques Bouchard, Bureau of Gastroenterology, Infection and Viral Diseases
Sultan Ghani, Bureau of Pharmaceutical Sciences
Brian Gillespie, Senior Medical Advisor Bureau
David Lee, Office of Patented Medicines and Liaison
Lesia Maruschak, PB
Roland Rotter, MDB
Paul Roufail, Bureau of Metabolism, Oncology & Reproductive Sciences
Marilyn Schwartz, BOS
Mike Ward, PB
Brigitte Zirger, Bureau of Cardiology, Allergy and Neurological Sciences

Secretariat
Gail Gervais, PB
Denise Quesnel, PB
Susan Tessier, PB
Chantal Tremblay, PB

Wednesday, April 9, 2003

TPD Boardroom, Room 2048
1600 Scott St.
Ottawa, Ontario

1. Opening Remarks

Jim Blackburn welcomed members to their first meeting since August 2002, the December 2002 meeting having been cancelled.

2. Review of record of August 28-29, 2002 meeting - accepted as circulated.

3. Review of agenda - accepted as circulated.

Dr. Peterson pointed out that the first day of the meeting is more condensed to allow ACM members to participate in the TPD Extended Management Retreat (EMR) of April 10. The format is a facilitated videoconference with the FDA discussing their experiences with project management in reviewing drug submissions, sharing information on training, performance targets, integration of project management activities and lessons learned.

4. TPD Today

Dr. Peterson introduced Omer Boudreau, TPD's Associate Director General.

Dr. Peterson outlined recent influences on TPD's direction. Stakeholders have clearly emphasized the necessity for improving the regulatory process for drug approvals. The September 2002 Speech from the Throne promoted "smart regulation" as well including a specific commitment on improved review performance. The Romanow Report also contained specific recommendations on the improvement of the review process. This has resulted in a specific commitment for federal funding over the next five years to build a more responsive and business like environment.

With the new resources, TPD's business transformation plan will include the hiring and training of new resources; the development of a more integrated approach to submissions; the introduction of project management; and the consideration of the decisions of other jurisdictions. Workload analysis will help better manage the review process. Our ability to staff on a permanent basis is creating more stable environment. The hiring of project managers and a project management approach to the review process

will allow tracking of submission progress at regular intervals. Experience with using external reviewers has been positive with respect to timeliness and quality, so we are discussing ways of building teams of outside experts who are familiar with our guidelines and practices. As well, we are exploring how we could access expertise in institutions. Pre-submission meetings with industry will allow us to plan ahead and receive direction on products under development and testing.

5. Special Access Programme (SAP)

A combined presentation was made on special access to both drugs and medical devices. The SAP is mandated to provide access to unlicenced therapeutic products (medical devices and drugs) to health care professionals for emergency use where conventional therapies have failed, are unsuitable or unavailable. These products are not released through retail pharmacies, rather, physicians must make application for their release. The vast majority of SAP requests are therapeutic products that are known to Health Canada; many have had interest generated through their clinical trials so there is some experience with the product in the community. Approximately 10% of requests are denied. Therapeutic products being withdrawn from the market due to unfavourable conditions are a challenge because they have a dependant patient group who has been using the product, which may be unique, for a significant amount of time. The SAP authorization does not constitute an opinion or statement that a therapeutic products is safe, efficacious or of high quality nor does the SAP conduct a comprehensive evaluation to ensure the validity of therapeutic product information from the manufacturer. It is the practitioner's responsibility to ensure that patients are well informed of the possible risks and benefits of the drug being requested.

6. Business Transformation

Kevin Doyle provided an overview of the key components of TPD's goal of achieving performance objectives in a sustainable manner. Business transformation is expected to establish direction, redesign business processes, introduce new technologies, provide training and continuously evaluate and improve the system. The result will be improved quality of submissions, review processes and decision making.

ACM members expressed their approval for this structure and process and congratulated senior management on their energy and commitment to making these necessary changes. It was acknowledged that the TPD is expert at managing crises but not necessarily in advance planning. It is important to have solutions at human resources level. Integrated risk management will engage review staff early consultation with experts or other regulators on safety issues.

7. MHPD Updates

(I) Risk Communication Survey

MHPD is conducting a survey to explore the attitudes and perceptions of the general public and health professionals regarding post-market drug safety information. The study objectives are to: inform on the effectiveness of current methods used to communicate new safety information about health products, collect baseline information to facilitate development of appropriate performance indicators and explore thinking regarding mandatory reporting of serious adverse reactions and informed patient consent. The need to link pre- and post-market data is recognized. It is felt that data communication to the public is best handled through a credible arms length organziation to address the issue of trust. Electronic data linkage will allow detection of signals early on and link to pre-market data. Health Canada is exploring accessing the database on adverse events which the FDA is using, however privacy issues are presently a barrier. Periodic Safety Update Reports (PURS) are not a requirement in Canada. The ACM was encouraged to send their comments on the surveys through the secretariat.

(ii) Communicating Drug Safety Information Workshop

The draft highlights and key messages report on the second Communicating Drug Safety Information: A Shared Responsibility Workshop was distributed. The vision is that responsibility for effectiveness of the system is shared among health professionals, industry, public and the regulator. Health Canada was advised to improve its information dissemination by listing indications along with adverse drug reaction information on its website. This initiative will link with the national Steering Committee on Patient Safety. This work will be done with representatives from health professional associations and health care groups. It was suggested that Health Canada should work with the Canadian Council on Health Services and Accreditation. The key suggestions from this workshop are being built into MHPD's operational plan. The ACM suggested that the health risk alert should be computerized and come up at point of purchase though the pharmacist to inform the patient know at point of care. Dear Health Care Professional Letters (DHCPLs) are an important way for Health Canada to communicate new safety information on marketed drugs. The development and issuance of DHCPLs involve a team approach led by MHPD.

8. International Reviews Update

TPD is exploring how to best use information from international reviews in the Canadian pre-market review process to address the timeliness of our approval system and make more informed decisions. The initial focus has been on the EMEA to learn from this centralized decision making process; a similar interaction with the FDA will be explored. ACM members were asked for feedback on the direction of this initiative.

It was commented that the Canadian regulator has less resources. TPD is attempting to adhere to timely review by increasing regulatory dialogue, adopting international best practices (such as the common technical document) and using reports from other agencies. The use of a formal, systematic approach to submission review may uncover things that are not necessary to do. We are presently examining whether the European system has the same confidence in terms of safety and quality. We participate in harmonization and regulatory cooperation by adopting an international common core of technical guidance which allows a common standard. It was noted that international agencies have greater activity in the area of procuring expert scientific advice early on to manage risk. Members acknowledged that opportunities to dialogue with Health Canada have always been there and that our input into sponsors' deliberations with other countries is well regarded. Sponsors appreciate working with global regulatory teams using common requirements documents so work is not duplicated.

9. Tabled Reports

(I) Quarterly Drug Submission Performance Report Oct. - Dec. 2002

Marilyn Schwartz reported that new drug submissions numbers have decreased over the last 2 years. The overall conclusion is that performance has improved in most areas. It is predicted that, due to the complex nature of new drugs in development, the reviews will be more complicated. An example is a combination product such as drug coated stents which require review, and perhaps clinical trials, in both the drugs and medical device jurisdictions. Health Canada received the same number of new molecular entities as the FDA (17), fewer than in previous years. There has been an increase in supplemental drug submissions. There are not that many new drugs in the pipeline so we are looking at new indications for existing approved drugs.

(ii) Medical Device Quarterly Report Oct. - Dec. 2002

The pressures in reviewing medical devices include a short product life cycle, tied to computer and technical advances. There has been a big increase in the number of applications for Class II medical devices (over 75% of total applications) resulting in this class being below performance standard. Applications for classes 3 and 4 were above performance standard, even though these reviews are more complicated. There is one licence for each device, although families or systems can share a licence. There is an increase in cardiovascular (class IV) investigational testing and submissions this year.

(iii) Advisory Committee on Electronic Submissions (ACES)

This initiative serves to engage industry and stakeholders in the shift toward an electronic review environment, driven by International Conference on Harmonization's (ICH) electronic common technical document (e-ctd). ACES is supported by an internal Working Group that involves Directorate within the Branch which deal with submissions.

Thursday April 10, 2003

Advisory Committee On Management (ACM) // Extended Management Retreat (EMR)
Chateau Cartier Resort, Gatineau, Québec

The ACM was invited to join the TPD's management retreat which would profile its project management initiative. More than 100 people attended. This meeting included participation by the Centre for Drug Evaluation and Research (CDER) of the Food and Drug Administration (FDA) in the United States which was hooked in through videoconference. Participants were asked to keep track of the key messages they heard throughout the day event. These messages were collected after each session and made available for use in subsequent discussions.

The goal of the day was to provide an overview of what project management means for the review process and how it fits into TPD's Business Transformation. Project management was examined from the perspectives of regulators (CDER) and stakeholders (ACM). There were five presentations, each followed by lively discussion periods.

Dr. Murray Lumpkin, Principle Associate Commissioner of the FDA, opened the CDER presentations. He said CDER began working on a project basis ten years ago to address the continual backlog of drug submissions and to better the review process. He said although the transition to a project management model was challenging, the resulting framework has been successful. He added that the framework is an evolving one. It is reviewed regularly to ensure it is allowing CDER to meet its targets. Further, the United States Congress reviews CDER's performance every five years. The key messages heard during Dr. Lumpkin's presentation are that

- Clear, reasonable goals and expectations need to be set;
- Timeliness is essential to "doing the job right";
- Accountability and predictability are essential to the regulatory process;
- A cultural shift is required to consolidate team-based and project management approach;
- Project managers are integral to the review process and their role is respected;
- A commitment is needed for adequate resources for the project management infrastructure, people, and procedures;
- It must be recognized the transition to a project management model is challenging; and
- Successes need to be celebrated along the way.

The ACM panel followed Dr. Lumpkin. The panel members described their experiences with project management, offering a wide variety of insights. The key messages were:

- Flexibility, effective communication and accountability are key to project management's success;
- Senior management must be involved in defining projects, reviewing progress, and priority setting;

- Project management requires an assortment of leadership types;
- Necessary project management skills must be developed;
- Projects need to be assigned according to skills;
- Potential roadblocks need to be identified as part of the planning process;
- It is okay to abandon failing projects;
- Milestones and decision points need to be differentiated; and
- Completed and closed projects should be celebrated

The next session was about roles and responsibilities of project management. Judith Milstein and Terri Rumble of CDER presented. Specifically, they said CDER implemented project management to improve review timeliness and increase transparency. They also explained the structure of CDER teams and the need for project managers. For example, project managers remove the administrative burden from reviewers and act as communication focal points both internally and externally. The presenters also talked about continuing hurdles to project management, as well as the lessons learned.

A panel of clinical evaluators put the CDER presentations by discussing how the project management model works from their perspective. Participants identified the following as the key messages from the review panel.

- Project management required careful examination of employee classification, pay and responsibilities. It is a major investment and significant commitment of personnel.
- Project management is invaluable, as it streamlines the review process and increases transparency. It also optimizes usage of expertise and is adaptable.
- The staff understands and values the project management approach.
- The team approach facilitates communication and integration across disciplines.
- Reviewers retain scientific authority.
- Project managers administer and coordinate project, allowing reviewers to focus on review. Project managers also provide consistency in regulatory affairs. It is advantageous for project managers to have a science background.
- Good documentation of decisions ensures continuity.

The final presentation of the day was about the interaction between CDER and industry. Sharon Olmstead, a liaison officer with Pharmacia, was the speaker. She talked about how industry project teams mirror those of the FDA. She also described how the roles of project managers in industry differ from those in the FDA. Although there are areas for improvement, project management has been valuable to industry-FDA relations, according to Ms. Olmstead.

Jim Blackburn thanked Bob Peterson and his management group on behalf of the ACM for allowing them the opportunity to participate and learn about project management.

Next Meeting: August 27-28, 2003.