Health Canada Santé Canada

Contact: Carolin Vaughn, Therapeutic Products Programme
Telephone No.:(613) 952-5321

MEETING NOTES
THERAPEUTIC PRODUCTS PROGRAMME
ADVISORY COMMITTEE ON MANAGEMENT

TPP Boardroom
Holland Cross, Tower B, 1600 Scott Street
Ottawa, Ontario
May 10-11, 2000

Members:
Jim Blackburn (Chair)
Lesia Babiak (May 11 only)
Luis Barreto
Andrea Baumann
John Blatherwick
Raphaela Borenstein
Robert Goyer
Stuart MacLeod
John Parks
Bonnie Salsman
Malcolm Seath
John Stewart
Beverley Townsend
Pamela Zabel

Regrets: Brenda Nunns-Shoemaker

Secretariat:
Dann Michols
Jan Pound
Denise Quesnel
Carolin Vaughn

Contributors:
Patty Birkwood
Don Boyer
Andy Butterfield
Marta Caris
Donna Daines-Hibbitt
Louise Déry
Ross Duncan
Julia Hill
Rosemary Nichols
Jean Peart
Karen Reynolds
Bruce Rowsell
Marilyn Schwartz
Heather Sutcliffe

Observers:
Susan Hasnain
Wayne Nitchuk
Bonnie MacLellan
Beth Pieterson
Roland Rotter
Brigitte Zirger

1. Opening Remarks (J. Blackburn)

Everyone was welcomed and the traditional roundtable of introductions was done. Stuart MacLeod was congratulated on his recent appointment to the Science Advisory Board (SAB).

2. Review of the December 8-9, 1999 Meeting Notes (J. Blackburn)

The meeting notes of December 1999 were approved as drafted.

3. ACM Membership (J. Blackburn)

Two new members have joined the TPP Advisory Committee on Management (ACM): John Blatherwick, a Medical Health Officer in Vancouver, nominated by the Canadian Public Health Association; and, Pamela Zabel, a nuclear pharmacist and assistant professor at the London Health Sciences Centre, nominated by the Nuclear Medicine Alliance.

New nominations from the Canadian Medical Association and the Canadian Pharmacist's Association are still pending.

4. TPP Status Report

4.1 Director General's Update (D. Michols)

Health Canada Realignment - An overview of the Department's current structure and its mandate was provided followed by the proposed structure. The proposed structure consists of seven (currently six) Branches and six regional offices (currently five). Essentially two of the existing Branches (Health Protection and the Health Promotion and Programmes) would be realigned into three Branches (Health Products and Food, Healthy Environments and Consumer Safety, and Population and Public Health). The objectives of this exercise are: to combine promotion, prevention and protection responsibilities in each Branch; to balance the Branches, their responsibilities and the resources assigned to them thus creating smaller Branches and Programmes whose operations are more manageable; and to integrate delivery of national activities in each region.

The Deputy Minister has assigned four champions to guide the Department in realigning its activities into the new structure by July 1, 2000: Diane Gorman, Health Products and Food; Dann Michols, Healthy Environments and Consumer Safety; Ian Potter, Population and Public Health; and Bill Pascal, Regional Operations. On July 1, 2000, the Deputy Minister will announce the management team to implement the realignment of the resulting structure.

The intention to appoint a Chief Scientist reporting to the Deputy Minister remains, but his/her role is still undefined. The realignment task team will be exploring this position further. The position of Chief

Scientist is seen as being more of an ombudsman for the Department's science capacity and not to be responsible for scientific operations per se.

The Health Canada Realignment will have an impact on all TPP activities. Communication mechanisms have been developed to inform and support the TPP staff during the realignment.

Legislative Renewal - Given the Minister's priority on the health care system and its funding, the new legislative proposal will not be going to Cabinet as expected this summer. The realignment will undoubtedly have an effect on legislative renewal, and the TPP will take this time to review the proposal in its current state and to prepare for stakeholder consultations to be held in the fall.

Drug Regulation "Summit" - As a follow-up to the activities over the last eighteen months motivated by the HIV/AIDS community, this event was held in Ottawa on May 8-9, 2000, and was organized and sponsored by industry, the HIV/AIDS community and the volunteer sector. It was noted that although TPP was represented at the meeting, this was not a TPP event. Presentations were made by the TPP and other international regulatory agencies. During the Health Minister's brief appearance at the conclusion of the Summit, he acknowledged and identified time lines, transparency and post-market surveillance as the three issues that need to be addressed to improve the drug licensing process. In summary, all parties including industry, patient groups, health professionals, and the regulators are dissatisfied with the current review time lines and are working towards a common goal or shortening them.

Frustration was evident amongst the ACM members as under-resourcing has already been identified through numerous studies to be the critical issue. The results and recommendations now need to be collectively acknowledged and actioned.

4.2 TPP Strategic Direction 2000-2001 (J. Pound)

Six strategic priorities for the TPP and the initiatives underway to address each of those priorities were presented. The strategic priorities are to rationalize the Programme, strengthen the organization, enhance performance, increase transparency, develop partnerships, and increase resources.

The members expressed interest in knowing the extent that improving time lines would actually have on the timeliness aspect of a review with/without additional resources, and questioned what was being done and what could be done. Streamlining/improving efficiencies will only make a 10-20% change to timeliness. Resources are needed in order to make substantial improvements to review times.

4.3 Financial Update (A. Butterfield)

An overview of the TPP's financial position was presented. An increase of approximately $35M (before taxes) in new Appropriations is anticipated; however, there are several uncertainties including the impact of the realignment, new funding, revenue, and the impact of Cost Recovery Phase IV. While two-thirds of the new resources will go to new and unresourced activities (i.e. Controlled Substances

and the Transplant Network), only one-third will go to strengthening the base of core activities measured by stakeholders. The Programme will need to look at more innovative ways to address review processes (i.e. harmonization, partnerships, streamlining, etc.) in order to decrease review times.

4.4 Human Resources (HR) Update (B. Rowsell)

An update was provided on the TPP Human Resources Discussion and Planning Document prepared by the Programme Management Committee on Human Resources (PMC-HR). Next steps include the development of a strategy and implementation plans for the short and long term.
A lengthy discussion followed on the challenges around the critical issue of staffing. Discussion points included:

- the difficulty in finding, recruiting, developing, and retaining employees in a competitive workforce
- the resulting loss and difficulty in maintaining expertise
- the need to explore other recruiting mechanisms and partnership opportunities
- the need to look at, and the challenges faced with, expanding the use of external expertise and international linkages
- the current lengthy staffing process (even when position and resources have been authorized)
- the need for Corporate HR Services to address (and deliver on) the customer/supplier relationship
- the drastic decrease in the relative availability of trained people over the next ten years

In conclusion, it was noted that many of these issues and processes will be explored in the context of the new Advisory Panel on the Product Licensing Review Process. With the support of the Deputy Minister, ACM members questioned the need to conduct an appropriate human resources study.

ACTION: *Invite Robert Lafleur, Senior Assistant Deputy Minister, Corporate Services Branch to the next meeting.* *Jan Pound*

5. Performance Updates - 1999 Annual Report / First Quarter 2000

5.1 Medical Devices Performance (D. Boyer)

An overview of the performance for medical device reviews for 1999 was presented. A fax-back form has been introduced to facilitate the review process. There is evidence of performance improvements for the first quarter of this year.

5.2 Drug Review Performance (M. Schwartz/M. Caris/J. Peart)

An overview was provided on the Programme's performance related to drug submission reviews for 1999 and for the first quarter of this year. Discussion followed on submission review performance and times, and the various contributing factors associated with not meeting the performance targets. Although the Bureau of Pharmaceutical Assessment (BPA) will be receiving funds to recruit fifty full-

time equivalents (FTEs), most of these new resources will be dedicated to clinical trial reform activities. There will not be enough of a resource increase in the areas of pre-market review to meet the expectations of stakeholders with respect to current performance targets.

6. Product Licensing

6.1 Follow-up to HIV/AIDS Working Group and SAB Recommendations (D. Michols)

A new advisory panel is being established to advise the TPP as it works through the recommendations of the HIV/AIDS Working Group and Consultative Workshop, and those of the SAB. The Advisory Panel on the Product Licensing Review Process will be chaired by Dr. Robert Goyer and its inaugural meeting is scheduled for June 6-7, 2000. The relationship between this Advisory Panel and the ACM was questioned. The ACM's mandate is to advise on the overall management of the Programme's activities, whereas the Advisory Panel will be limited to advising the management on implementation of the two sets of recommendations as they relate to the product licensing process. It was proposed that the ACM would act as an oversight committee to the Advisory Panel and Dr. Goyer would provide the link between these two groups.

6.2 Centre for Medicines Research (CMR) Survey on Quality Assurance of Drug Reviews (J. Pound)

In collaboration, the reviewing bureaux of the TPP completed this multi-regulatory agency survey. The data collection will allow the CMR to make comparisons of quality measures used across different regulatory authorities, and will enable the level of the investment of authorities in quality assurance to be ascertained.

6.3 Functional Review of Drug Screening Process (P. Birkwood/M. Caris)

To address the concerns expressed by stakeholders regarding the nature and timeliness of screening, a functional review was undertaken in 1999/2000 to look at the BPA's screening process of drug submissions. An overview was provided on the approach and activities used to conduct the review. In order to begin any change process, next steps include: the Bureau of Pharmaceutical Assessment giving careful consideration to the consultant's findings and recommendations with regards to feasibility, priority and implementation; general consultations with staff and industry; a presentation of recommendations and implementation plan to the Programme's Management Committee for approval.

There was discussion on the value of the screening review process now that submissions are 90% compliant. It was suggested that screening resources could be used to educate industry to further increase the quality of submissions.

ACTION: *For next meeting, present actual times used in each phase of review process.*
J. Hill/M. Schwartz

6.4 Functional Review of Medical Device Application Process (D. Boyer)

A quick update was provided on progress to date. The review started on March 1, 2000 and included extensive interviews and work sessions with management and staff to map current processes and to identify areas of improvement in consistency, transparency and efficiency. The contractor will finalize the report by May 15, and this will be reviewed by TPP for appropriate action.

6.5 Functional Review of Regional Adverse Drug Reaction (ADR) Centres (H. Sutcliffe)

The Regional ADR Centre Functional Review was conducted to reassess its value and need; to identify optimal roles and responsibilities; to rationalize resources and expectations; to identify organization options and potential formulae for payment; and to determine organization and appropriate number of Regional ADR Centres.

As a result of the review's findings and recommendations, the next steps/implementation phase include focussing on the following areas: a strategic/business model of the ADR Program; operations management; information, promotion and partnering; and information management/technology.

Discussion followed regarding the ADR Program's current structure and possible options for future reporting functions, how it's resourced, and its relationship to the new departmental realignment.

6.6 MotherNet Project (B. Rowsell)

Due to time constraints this item was not presented. (The initial phase of this project will be to develop an effective system to collect information on potential risks and benefits to drugs used in pregnancy; to create a database by starting with information collected at current MotherRisk clinics in Toronto and Montreal; and to provide information access initially to clinical decision makers (health care professionals) and regulators. The population and public health areas of the Department have the lead on this project.)

6.7 Medication Errors Project (B. Rowsell)

The background and considerations for this proposed project were presented. The project would look at reporting medication errors separate from adverse events.

Feedback from the Committee was requested with regards to whether or not the TPP should take on this initiative. In summary, the members agreed that although it is a national public health issue and needs to be done, it is not part of the TPP's mandate to deal with medical best practices. The TPP has too many of its own priorities that need resourcing. It was recommended that this initiative also be looked at by both the Provincial Ministers of Health and the Medical Officers of Health.

To move the initiative forward, the Canadian Society of Hospital Pharmacists (CSHP) has offered to organize a planning meeting at the end of May for a fall workshop that will look at the issues with a wider range of stakeholders at the table.

7. Canadian Institutes of Health Research (CIHR)

7.1 Activities of Interim Government Body (A. Baumann)

The legislation has been completed and was passed in April. The design of the institutes is in place and the president and new council will be named shortly. There is a strong focus for science activities. The opportunity still exists for the TPP to collaborate with academia and industry to prepare a discussion paper for a future institute proposal. The CIHR is expected to be launched and operational in the next six to seven months.

7.2 Canadian Paediatrics Society: Drug Investigation for Children (S. MacLeod)

Report from the meeting held in April will be released shortly. It is anticipated that a CIHR institute encompassing children's, women's and senior's health will be created. A Canadian Paediatric Clinical Trial Network could also be established. Incentives could be developed for manufacturers willing to do this research.

ACTION: *Update to be provided at the next meeting* *S. MacLeod*

8. Regulatory Updates

8.1 Clinical Trial Reform (K. Reynolds)

Issues of concern identified through publication in the Canada Gazette Part I were presented. The redrafted regulations will be published in Canada Gazette, Part II in June. The implementation date of September 1, 2000, remains the same as originally scheduled.

The members questioned if the TPP would be ready for implementation on September 1 given the inevitable impact on resources and other submission work. The Programme has been preparing for the anticipated increase in workload.

8.2 Mutual Recognition Agreements (MRA) with the EU and Switzerland (L. Déry)

The confidence building exercise with Switzerland will be completed on May 31, 2000. The regulatory authorities of both parties have been deemed equivalent. The MRA with Switzerland is expected to be in full operation by July 2000. A two-year programme to build confidence in the area of pre-approval inspections has been agreed to.

The confidence building exercise with the European Commission is progressing well. The equivalence evaluation is expected to be completed by the end of June 2000 and the transitional period is anticipated to be completed by mid-July 2000. The MRA should be operational by early September. Agreement with the EU for a two-year confidence building programme for pre-approval inspections was also reached. The next meeting for the Joint Sectoral Group is planned for July 2000.

Negotiations with the Treasury Board have resulted in $1.5M to implement further MRAs. Canada and Japan (Ministry of Health and Welfare) have agreed, in principle, to undertake joint activities. A plan of action has been signed for exchanging information between the TPP and the State Drug Administration in China.

8.3 Environmental Assessment Regulations

Due to time constraints this item was not discussed at length.

ACTION: *A briefing note will be sent to the members* *Julia Hill*

8.4 Standards Based Regulation

Due to time constraints this item was deferred to a future meeting. (Copies of the slide presentation were provided.)

9. BTOX (Blood, Tissue, Organs and Xenografts) Update

Due to time constraints these updates will be provided at a future meeting. (Copies of reference documents and slide presentations were provided.)

10. Transparency Initiative

10.1 Overview (J. Pound/R. Nichols)

For a number of years the TPP has undertaken a wide range of initiatives to enhance the transparency of its decisions, activities, and processes. However, the Programme is still often criticized for not being transparent enough, especially in relation to the drug review process. The TPP intends to find out why this is and take action. A transparency strategy is being developed that will cohesively link all of the TPP's activities as they relate to: consultation mechanisms, communications, information dissemination and public involvement. A Transparency Task Force has been established and activities are already underway to address some of the identified transparency issues.

ACTION: *Members requested to provide comments on the draft transparency strategy and action plan.* *All members*

10.2 Outcome of the Workshop on the Public Advisory Committee (PAC) (C. Vaughn)

The PAC Workshop was held on April 17-18, 2000, with the objectives of increasing awareness and understanding of the TPP and to validate the proposed concept of a PAC. Overall, the Workshop was well received by the participants and the general message was that public involvement with the TPP is an important initiative and the Workshop was a positive start. Next steps towards moving forward include the refinement of the draft terms of reference for the PAC by a voluntary subgroup and the establishment of a Working Group which will convene in the fall to continue with the concept and development of a PAC.

As was raised at the Workshop, the Committee also questioned the relationships between various public involvement initiatives at the Programme, Branch and Departmental levels. The clarification of roles and relationships will become clearer as the Office of Consumer Affairs and Public Involvement (OCAPI) establishes itself within the Branch/Department. The TPP is represented on the OCAPI Task Force.

10.3 Communications (D. Daines-Hibbitt)

There has been extensive activity regarding the TPP's communications efforts since the last update provided to the Committee. Highlights include the fact that a dedicated resource has been secured to concentrate on the development of the TPP web site; fourteen TPP Fact Sheets are now posted on the web site; the launching of the TPP's quarterly newsletter *Rapport*; strategic elements of the draft Communications Strategy are being incorporated into the Programme's activities; the Programme's successful participation at the Pharmaceutical Sciences Group (PSG) exhibit/information exchange; and the on-going internal communication vehicles geared to keeping staff updated on realignment activities.

10.4 Information Dissemination Activities (R. Duncan)

The TPP is dealing with a number of information-related issues (i.e. the internet sales of therapeutic products; direct-to-consumer advertising; retention/control of information). As part of the transparency initiative, the TPP is looking at how best to integrate these activities in a coordinated fashion. Suggested next steps to address information dissemination issues include setting standards, enhancing educational activities, and developing dissemination programs.

11. Meeting Evaluation and Closing

The members discussed next steps which could be taken by the Committee to support the TPP in the delivery of its programme.

Next meeting: **August 23-24, 2000** (10:00 a.m.)
TPP Boardroom, Room 2048, 1600 Scott Street, Holland Cross, Tower B

Proposed Schedule of Meetings for Year 2000:
December 6-7, 2000

Original signed by

Jim Blackburn
Chair