PAAB Happenings

The Pharmaceutical Advertising Advisory Board

REVIEW

Ray Chepesiuk,
Commissioner

A few years ago, somebody told me he liked to read my newsletters and articles because it gave him an indication of what would be changing in a year from now. So, I thought it would be a good idea to let people know what is happening at the PAAB these days. There are a number of activities and projects going on that may lead to changes and perhaps I can give you some insight into the PAAB future.

Staffing

I am privileged to work with a great group of people at the PAAB office and more will be joining us shortly. We have grown considerably in the past few years and change is inevitable. Our challenge is to get these great individuals to work together as a great team. With this as our goal, the Board took the opportunity to change the functional alignment of the PAAB in 2005. We recently got around to changing the titles for positions.

In late 2005, the PAAB hired a human resources firm to evaluate the positions at market value and staff salaries were adjusted for 2006.

Commissioner: Ray Chepesiuk
The Commissioner heads up the staffing and is responsible for all that is the PAAB, from an operational point of view

Chief Review Officer: John Wong (former Deputy Commissioner and Senior Reviewer)

- This is a functional manager position and the incumbent reports to the Commissioner
- The Chief Review Officer is responsible for the operation of the review function, from a quality consistency and efficiency perspective. He is responsible for reviewing training and productivity, along with client relations

Reviewers: Colin Campbell, Yin Man, Lucia Kim, Pauline Dong, Patrick Massad, Karen Rizwan, Chris Seto and Ellen Fan (formerly called Assistant Commissioners, they report to John Wong)

- Reviewers are responsible for the review of the PAAB submission files and customer service

Office Manager: Glenn Golaz

- This is the second functional manager position reporting to the Commissioner
- The Office Manager is responsible for the administration of the PAAB office and the PAAB preclearance review mechanism,

information technology systems and accounting

Administrative Assistants:

Estelle Parkins: reception, data entry and communications

Laurie Johns: data entry and file management

Sabrina Hack: part-time employee

- The Administrative Assistants report to the Office Manager

Workload

Review volume

The PAAB staff has been busy with review volume increases in each of the last five years. Due to staffing adjustments, we have managed to keep the average number of reviews per reviewer fairly steady (the range is between 626 and 653) until this year, when we projected a large annual increase of 80 reviews per reviewer. Looking back on the PAAB during the 1990's, we had unpredictable increases and decreases. So, the past five years have been unusual in the 30-year-history of the PAAB. I think a significant contributing factor to the review volume increases has been the heightened industry awareness of guidelines along with compliance and the implicit support of the PAAB self-regulation preclearance review mechanism.

I think a significant contributing factor to the review volume increases has been the heightened industry awareness of guidelines along with compliance and the implicit support of the PAAB self-regulation preclearance review mechanism.

Turnaround time

We are working on improving our turnaround of submission records. We have added two reviewer positions this year and we hope that they will help to address the increased workload. We are also trying to get data on our workload to help us with a project designed to assign specific therapeutic area products to specific reviewers. We believe that we have enough reviewers to be able to do this. We also see potential benefits in improved consistency, targeted training and reviewer accountability. Analyzing what we have done in the recent past will help us to build a plan for the future.

Electronic submissions

We have started a project to assess the feasibility of setting a PAAB standard for electronic web-based submissions. Presently, we receive a mish-mash of electronic submissions and we would like to standardize the process to provide increased efficiency in the service we provide to our clients. We have engaged a consultant to assess our needs, with a view to adapting proprietary software. We will set a proposed implementation date for this project when we get more information from the consultant. Potential benefits include:

- reduction of administration time,
- clarity of the submission material for review,
- improved workload measurement,
- improved PAAB/client communications and
- staff satisfaction.

Code revision

The PAAB is in the midst of trying to finalize a code revision regarding PAAB Code requirements for benefit/risk, fair balance and prescribing information (PI). This topic was initiated in the 2004 Code review process and it was decided that it was too complex to be

completed for the April 2005 implementation, along with the other revisions. A new format was proposed by the Code committee after research on the current format was done. Forty-eight Canadian physicians revealed that the PI could be more useful as a reference tool. The new format was subsequently tested with 100 physicians and the results were so convincing that the new format was seen as an improvement over the existing one, which had been in place since the inception of the PAAB Code (see the PAAB Review in the June issue of *Canadian Pharmaceutical Marketing*).

At the time of writing this article, we were starting a consultation of 455 stakeholders. The goal is to have the PAAB members vote on the Code Revision on November 24, with implementation projected for the Spring of 2007 or later. There may be other changes in the code identified during this process. Keep in mind that fair balance of risk-to-benefit information is still required in the main advertising message and some of the information may be moved into the PI Summary Box.

Files for review

We are looking to strengthen the requirement that a sponsor's final approval be signified by a signature from medical-regulatory. Despite the checkbox on the submission form that we instituted several years ago, we are still receiving incomplete files for review. Some agencies send revised files a week after we received the original file and before we have completed a first review. The PAAB will review complete, final copies as quickly as it can. We may have to institute a time penalty on agencies that abuse this principle, by counting the last revision as the "complete" date and bumping the file back in the queue.

Other projects

The PAAB

The PAAB is currently doing preparation work for an upcoming PAAB strategic planning project that will begin later in 2006.

External projects

As PAAB Commissioner, I have also been invited to participate in the following projects:

- I have been an advisor in the OntarioMD internet project that involves a number of PAAB's pharmaceutical clients
- I have been asked to take part in a US working group regarding setting standards for patient education and materials with the goal of possibly adapting those standards for the purpose of the PAAB Code of Advertising Acceptance. (The code currently requires review of patient information created and distributed by healthcare product companies)
- The PAAB has been approached by a medical academic body to assist in the regulation of "educational" meetings that are funded by the pharmaceutical industry and that are not accredited
- I have been invited to moderate an international panel at a September conference in Philadelphia to discuss the topic of how Off-Label Use is handled in countries other than the US (even US pharma is admitting it can learn from other jurisdictions!)

Final comment

I hope this overview helps you become aware of some of the activities going on at the PAAB this year. Some of the activities may be a preview for future PAAB Code changes because that's what it's all about. CPM