Pharmaceutical Advertising Advisory Board

PAAB 1998 Report

COMMISSIONER'S REPORT

Consistent turnaround times

During 1998, the PAAB staff sustained the significant improvement in the efficiency of PAAB's reviewing operations that was achieved in 1997.

Despite the Code requirement of ten working days, the PAAB Commissioner stated publicly that the 1998 operating target was to complete the initial review within one week of receipt of a complete submission. PAAB reviewers hit the mark on 94% of reviews; and 100% were in 8 working days or less.

This record was accomplished despite a tremendous surge of reviews in November and December coincidental with the loss of PAAB's Senior Reviewer, Ray Chepesiuk who took on the role of Interim Commissioner. The staff members met the challenge set by the Commissioner.

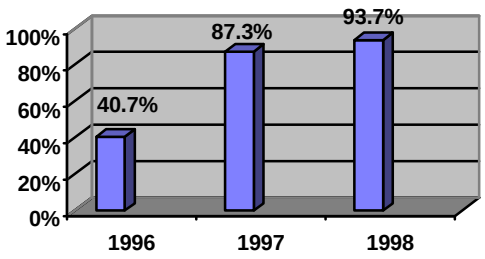
The major factor in achieving this record was having a stable and experienced review staff. The 5 permanent reviewers were assisted by the timely availability of two former PAAB reviewers who filled the gap during parental leave and the loss of the Senior Reviewer. Jane Shum and Colin Campbell stepped into the Senior Reviewer role in a fine manner.

Second year Reviewer, Joanna Rizos and 1998 arrival, John Wong progressed to become effective reviewers. The review contingent is well supported by Submission Coordinator Carol Johnston and Receptionist /Secretary Estelle Parkin.

The first review turnaround target of ten working days or less is the PAAB goal for 1999. Shown below is the major improvement in submissions reviewed in five or fewer calendar days; from 40.7% of files in 1996 to 87.3% in 1997 and to 93.7% in 1998.

This report was tabled at the PAAB Annual General Meeting on April 9, 1999, and is also being distributed more widely in a newsletter format.

Share of ads reviewed < 5 days



This report sets out a wide range of activities in which PAAB was involved during 1998 – including complaints resolution, monitoring, Direct-to-Consumer Advertising of prescription medicines advisory, and policy activities with regard to standards for comparative claims – as part of its role of ensuring that Canadian pharmaceutical advertising is accurate, balanced and evidence-based.

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Comparative claims standards approved

The Health Protection Branch released a document in January of 1997 as part of its initiative to clarify comparative claims standards for drug advertising to consumers and health professionals.

After receiving comment from several organizations including the PAAB, the HPB replaced its January 1997 document with *"Principles for Comparative Claims Related to the Therapeutic Aspects of Drugs",* dated May 1997. That document states that the PAAB is responsible for implementation of the principles related to drug advertising to health professionals.

PAAB's Board subsequently agreed to proceed to revise its Code – Section 5, Comparative Claims – to incorporate the principles. The Board launched an extensive consultation process during 1997and into 1998.

The revised section helps to clarify what data is required to support comparative claims. Since 1995, PAAB reviewers' practice has been to require peer-reviewed, head-to-head trials in support of comparative claims of safety and efficacy. Clearer Code wording should send a signal to advertisers to improve the quality of ad submissions.

PAAB will continue to accept 'restricted' claims based on the presentation of data from one comparative study but extrapolation of the claim beyond the actual conditions of the supporting studies is not acceptable.

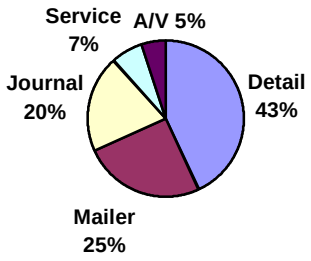
Submission volume slows down

A total of 2,350 human pharmaceuticals submissions were reviewed in 1998, down 7% from the previous year. This decrease breaks the recent trend of increases started in 1995.

The mix of submissions shows single-page journal ads comprised 20% of the total, towards lengthier detail aids (43%), mailers (25%), audio-visual materials (5%) and company-sponsored materials with an educational orientation (7%). I note that a heavier workload has resulted from the many multi-paged detail aids that can include extensive substantiation material.

In 1998, submissions were received on behalf of 85 manufacturers or advertisers, and from a total of 121 advertising agencies.

1998 Review Mix



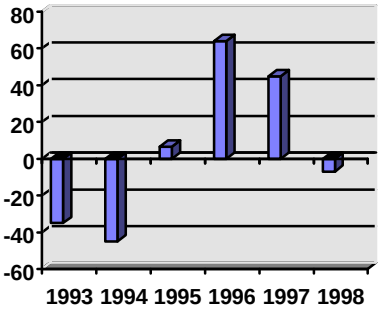
Stable financial picture

PAAB is a not-for-profit organization that does not receive direct grants from any source, but charges a fee to advertisers for the review of each submission.

In 1998 PAAB saw a slight deficit of $5,000. Revenue during the year was $763,000, down from $777,000 in 1997. There was no fee increase in 1998. The majority of PAAB 1998 expenditure of $768,000 provides for salaries, that included a complement of five reviewers during the full year for the first time.

The 1999 budget will include a 5% fee increase to cover the basic costs and additional expenditures related to the upgrade of the computer network and the search for a new Commissioner.

PAAB Surplus (Deficit) Position



Veterinary drug ads

In an arrangement with the Canadian Animal Health Institute (CAHI) and Health Canada's Bureau of Veterinary Drugs, PAAB has since 1989 reviewed journal advertising directed to veterinarians, producers and consumers. In 1998, 86 ads were reviewed, a similar number to the 87 reviewed in the previous year.

PAAB's arrangement in the veterinary drug field does not involve responsibilities with regard to monitoring. The Canadian Animal Health Institute actively promotes preclearance among its members through its Code of Marketing Practices.

Complaints and monitoring

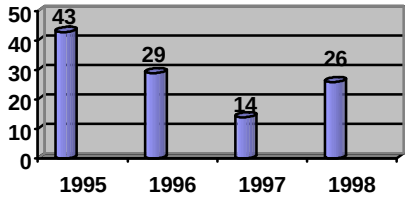
During 1998, the PAAB Commissioner processed 26 Stage 2 **complaints**. This number contrasts to 14 in 1997, 29 in 1996, and 43 complaint rulings by the Commissioner in 1995.

Of the 26 complaints, 18 were generated from advertising that had been previously PAAB-reviewed; 8 of these complaints resulted in withdrawal of PAAB's previous acceptance (PAAB reviewed 2350 advertising pieces in 1998). Ten complaints were rejected. Of the 8 complaints on advertising that was not PAAB-approved, 7 were sustained. One of these complaints was referred to PAAB by the Therapeutic Products Directorate (HPB). Under the Directorate's policy, the PAAB Code process is the initial avenue for complaint resolution, even for advertising not sent initially to PAAB for review.

- 22 of the Stage 2 complaints were disputes between pharmaceutical companies, many in highly competitive therapeutic categories such as cardiovascular medications, antibiotics and pain medications. 3 were initiated by Health Canada and one came from the Ontario Ministry of Health.
- 4 of the complaints concerned OTC products (2 were sustained); the remainder were Schedule F Part 1 (prescription drugs) and one vaccine.
- 11 of the 26 complaints were for new products less than two years on the market.
- 8 of the 15 complaints that were sustained involved comparative claims.
- 6 offences were based on insufficient evidence; 4 offences for not sending it to PAAB for review.
- 8 of the complaints that were sustained involved journal ads; 4 detail aids; 2 mailers and 1 video.

Most sustained cases concluded with withdrawal of material as a penalty. One correction notice penalty was assessed.

Stage 2 Complaints



During 1998, PAAB continued to regularly **monitor** journals, the Internet, and receive direct-mail/detail aid materials collected by health professionals as part of its monitoring program. In the past year, a total of 16 monitoring letters were sent, most relating to unreviewed advertising materials containing misleading or off-label claims, lack of balancing risk/benefit information, or the absence of detailed prescribing information. All of these ads were either withdrawn or resubmitted for PAAB review. One advertiser was required to publish a retraction notice. When warranted, cases are referred to the respective trade associations for appropriate action and/or reported to Health Canada in accordance with the PAAB Code.

DTCA activities

During 1998, Commissioner McElwain and Interim Commissioner Chepesiuk were involved in several activities relating to Direct-to-Consumer advertising of prescription medicines. On numerous occasions, the Commissioner made presentations at open conferences and private mini-workshops at individual companies, on the current regulatory environment and the potential role of the PAAB as a review mechanism. The PAAB provided opinions on the acceptability of proposed non-branded advertising to consumers. Also, the PAAB Commissioner provided a free advisory service to media, third-party service providers and sponsoring advertisers on the current regulatory environment.

Staffing and Training

PAAB's current staff of five professional reviewers is set out below. During the year, former reviewers **Helen Breedon and Sam Kim** agreed to complement our review staff in time of need. Reviewer **Jane Shum** was on maternity leave from March until July 1998.

In January, 1998, **John Wong** joined our full-time staff. John is a graduate of the faculty of pharmacy at Université Laval, Québec, and worked as a hospital pharmacist for five years before owning a community pharmacy in Toronto.

Our training efforts to upgrade and maintain staff competencies continued in 1998. PAAB supported individual self-learning efforts and attendance at conferences. Several reviewers accompanied the Commissioner to make presentations at mini-workshops that were requested by PAAB clients. This allows them to improve speaking skills, meet our clients and answer their questions.

Workshops for advertisers help to widen their knowledge on how to prepare submissions that meet the PAAB Code standards.

Planning was begun for a February 1999 PAAB reviewer training program in conjunction with a clinical epidemiologist from the University of Western Ontario.

PAAB staff

Commissioner:	vacant
Interim Commissioner:	Ray Chepesiuk
Reviewers/Assistant Commissioners:	
	Colin Campbell
	Joanna Rizos
	Jane Shum
	John Wong
Submission Co-ordinator:	
	Carol Johnston
Administrative Support:	Estelle Parkin
Accounts:	Glenn Golaz

All can be reached at (905) 509-2275.

Search for PAAB Commissioner begins

PAAB Commissioner Mark McElwain resigned his position October 31, 1998. At the October 30, 1998 General Meeting, he was officially thanked by the Board for his diligence and achievements as Commissioner of the PAAB. The Board set up a Search Committee with members: Chair Reg Perkin, Dave Skinner, Gloria Bowes, Greg Hines and Phil Diamond. The role of the Committee was to set criteria for the Commissioner position and after appropriate solicitation and screening of candidates, to make a recommendation to the Board in early 1999.

Which groups make up the "Board" in PAAB?

Advertising Standards Canada
Association des médecins de langue française du Canada
Association of Medical Advertising Agencies
Association of Medical Media
Canadian Drug Manufacturers Association
Canadian Medical Association
Canadian Pharmacists Association
Consumers' Association of Canada
Nonprescription Drug Manufacturers Association
Pharmaceutical Manufacturers Association of Canada

(Health Canada is an ex-officio observer.)

PAAB: need more info?

PAAB is an independent review agency whose primary role is to ensure that advertising of prescription drugs is accurate, balanced and evidence-based. The scope of the PAAB Code currently includes advertising of prescription and OTC products to health professionals, in all media.

For information or if you have comments:

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***The PAAB Code of Advertising Acceptance** and **PAAB Supplementary Guidelines** are available at:*
http://www.*paab.ca*

*These key **HPB documents** can be found at **http://www.hc-sc.gc.ca/hpb-dgps/therapeut/drhtmeng/policy.html**:*

- *Advertising and Other Activities, Distinction of*
- *PAAB and Drugs Directorate Roles and Consultation re Advertising Review*