Pharmaceutical Advertising Advisory Board

PAAB 1996 Report

COMMISSIONERS REPORT

"Substantial progress in strengthening PAAB"

This report was tabled at the PAAB Annual General Meeting on April 4 1997, and is also being distributed more widely in a newsletter format.

PAAB went into 1996 with a two-year plan, setting the four following goals:

- raise awareness and strengthen compliance
- clarify review standards
- streamline operations
- respond to the changing scope of promotion

The results in 1996, an active year on many fronts, show substantial progress in each of these areas.

Efforts to streamline operations have yielded a substantial improvement in review turnaround times.
During the last quarter of 1996, time-to-initial-review dropped from the 3-4 week range to under two weeks, a pattern that has continued into 1997.

Revised Complaints and Appeals procedures were implemented in May 1996. The revised process encourage resolution between advertisers and complainants, but provide a clear mechanism for an external ruling when required.

To clarify review standards and help the Code adapt to changing promotional practices, PAAB issued supplementary guidelines. One addressed PAAB's clearance standards in the use of Product Monograph data in comparative claims. Another aimed to clarify the boundary between advertising material requiring review, and independently-produced educational reports.

It was a year with a substantial budget surplus, continued training of PAAB reviewers, and of advertising submitters in PAAB-led workshops.

It was a year in which PAAB started raising awareness of its role via newsletters and the beginnings of a web-page presence on the internet.

PAAB's current self-regulatory role in the preclearance of pharmaceutical advertising to health professionals has become more widely understood. 1996 saw the publishing by the Health Protection Branch (HPB) of a policy paper that clarified the roles and responsibilities between PAAB and the Drugs Directorate of HPB. The working relationship between the two organizations consolidated the improvements achieved the previous year.

PAAB's role is to ensure that pharmaceutical advertising is accurate, balanced, and evidence-based. At the same time, self-regulation has become more established internationally and in Canada as the mechanism of choice to ensure advertising accuracy.

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Commissioner's Report
(Continued)

As a result, it is not suprising that PAAB has been closely involved in discussions on the potential form of self-regulation, should our federal government revise its restrictions against advertising of prescription medicines direct-to-consumers.

PAAB plays an important role in a dynamic field. This takes an understanding of the science, public policy and the marketplace. PAAB's progress in 1996 aims at maintaining that balance, achieving gains both in effectiveness and efficiency.

Major gains in turnaround times

1996 saw a substantial improvement in the turnaround time for initial reviews.

Our tracking system reported that 66% of submissions received their initial review within 15 calendar days of arriving at the PAAB office in 1996, and 98% met the 30-day performance standard officially set in the PAAB Code. This is an improvement from 62% and 97% in 1995.

However, the PAAB recognizes that the 30-day official performance standard, set a number of years ago, does not reflect today's deadline pressures the industry faces.

PAAB announced a Service Improvement Initiative in October 1996, starting with a questionnaire to determine user needs. Companies and agencies agreed that 30 days was not quick enough, and the survey results gave PAAB good data on firms' recommended solutions.

In the meantime, during the last quarter of 1996, turnaround began to show a major improvement. Until October, turnaround to first review tended to be in the three-to-four week range. However since October, turnaround times have dropped to less than two weeks (and often as little as one week), even through the peak December rush.

In order to ensure that turnaround times continue at this improved level, the PAAB Executive approved additional staff hiring, taking the review staff level from four to five. A reduction in PAAB's formal performance target (likely moving to a new standard of 10 working days) will be proposed shortly.

Submission volume grows by 8 per cent

A total of 2,435 human pharmaceuticals submissions were reviewed in 1996, up eight per cent from 2,261 in the previous year.

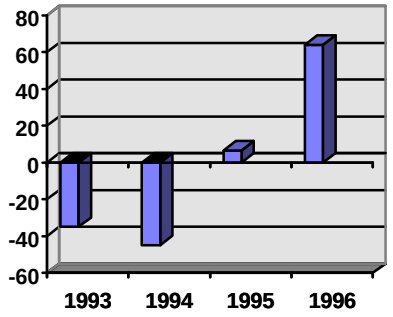
The mix of submissions continues to shift away from single-page journal ads (now comprising less than 20% of submissions) towards mailers, audio-visual materials and company-sponsored materials with educational content.

Financial turnaround

PAAB achieved an operating surplus of more than $63,000 on revenues of $695,000 -- compared to a small surplus of $6,000 in 1995 and deficits the previous two years. This improvement helps strengthen PAAB's balance sheet and flexibility.

The improvement from 1995 is largely a product of the increase in submission volumes. Expenditures were held almost level in 1996, and the average fee per review increased by only 0.4% in response to the new "tilted" fee schedule. (see next page)

PAAB Surplus (Deficit) Position



Veterinary ads

As a contract service, PAAB staff also preclears veterinary journal ads through an arrangement with the Bureau of Veterinary Drugs and the Canadian Animal Health Institute. In 1996, 48 advertisements were reviewed, and 2 intercompany complaints adjudicated.

Complaints resolution

During 1996, the PAAB Commissioner made 29 complaint rulings, compared to 43 Commissioner's rulings in 1995. Of the 29 complaints, 12 were generated from advertising that had been previously PAAB-accepted; four of these complaints were sustained.

- one complaint resulted PAAB requiring an erratum notice to be carried on all promotion for 12 months. The advertiser complied.
- 23 of these complaints were disputes between two pharmaceutical companies, many in highly competitive therapeutic categories.
- one 1995 complaint was appealed to an oral external panel hearing, and was held in 1996 using new panel guidelines. One 1996 Commissioner's ruling was appealed, and was heard by the Board of Directors.
- the most frequent compliance problem (concerning ads not sent to PAAB for review) relates to non-journal advertising such as mailers or sales materials from smaller companies. While most advertisers respond to complaint rulings, public reporting of non-compliant firms could help act as a deterrent.

The Revised Complaints and Appeals Procedures can be obtained from the addresses on this page.

The 1996 "Tilt" to the fee schedule: results

Effective January 1996, a revised fee schedule was instituted to link more closely to the actual time spent on reviews.

This policy resulted from the Commissioner's concern that reviewers were spending an inordinate proportion of their time on a relatively smaller number of submissions. Some advertisers seemed to expect to "negotiate" for PAAB approval, while other advertisers with approvable ads were forced to wait in the queue.

The revised fee schedule was designed to change the incentive structure for the 23% of submissions in 1995 that required 3 or more resubmissions before PAAB approval could be given. Those files face a 25% "extended review fee", while other files enjoyed a fee reduction by an average of 5%.

"Tilting" Fees: results

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The objective was to "tilt" the schedule to encourage first-draft compliance.

We are pleased to report positive results from this experiment. The object was not to raise more money from this change in the fee schedule: the average fee per submission increased only 0.4% year-over-year.

In fact, the proportion of ads requiring 3 or more resubmissions has fallen from 23% in 1995 to 20% in 1996.

Along with other initiatives to encourage review quality (including the request for Medical/Regulatory signoff before submission), reviewers see signs of an encouraging trend that may yield both higher-quality advertising and a streamlined review process.

PAAB "Roadshow"

The PAAB Commissioner and Deputy Commissioner have given overview/background presentations to associations and firms with direct or indirect involvements in pharmaceutical advertising.

While a slideshow on self-regulation may not be right for every audience, we see outreach as part of our role. Details, and our fee policy, are available from the PAAB offices.

Staffing and Training

PAAB's current staff of four professional reviewers plus the Commissioner are set out below. In early

Want more info on PAAB?

We're an autonomous, multidisciplinary body formed in 1975 that conducts independent review and preclearance of pharmaceutical promotions (prescription and nonprescription) directed to health professionals.

For information or if you have comments:

Pharmaceutical Advertising Advisory Board
375 Kingston Road, Suite 200
Pickering, Ont. L1V 1A3
tel: (905) 509-2275 fax: (905) 509-2486
e-mail: mcelwain@cycor.ca

The PAAB Code of Advertising Acceptance (including the revised Complaints and Appeals procedures) is also available at: http://www.pps.ca/PAAB/home.html

January, Colin Campbell joined our staff. He is an M.Sc. graduate who has worked in regulatory affairs departments of both CDMA and PMAC companies.

Sam Kim, reviewer since 1994, left the review staff mid-year to pursue graduate studies.

Jane Shum, a pharmacist with hospital experience, and most recently with the Ontario College of Pharmacists drug information centre, joined PAAB staff in June.

Our training efforts to upgrade and maintain staff competencies continued in 1996. In addition to individually-directed efforts, all reviewers and the Commissioner participated in a special session on appraising statistical methods, held in the PAAB offices, led by Professor Tom Einarson of the University of Toronto Faculty of Pharmacy.

We also continue PAAB's tradition of holding Toronto and Montreal workshops for industry to improve knowledge on how to prepare ads that meet the PAAB Code standards.

Who are the PAAB staff?

Commissioner: Mark McElwain
Deputy Commissioner and Senior Reviewer: Ray Chepesiuk
Reviewers/Assistant Commissioners: Helen Breedon, Colin Campbell, Jane Shum
Submission Co-ordinator: Carol Johnston
Administrative Support: Estelle Parkin
Accounts: Glenn Golaz

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

PAAB Supplementary Guidelines (available from the PAAB offices)

October 1992: *Antibiotic Guideline*
July 1995: *Supplementary PAAB guideline for advertising estrogen-progestin combination oral contraceptives*
July 1996*: Guideline on Educational Meeting Reports*
October 1996*: Guideline on Use of Product Monograph Data in Comparative Claims*
December 1996*: Guideline for the Conditional Review of Pre-NOC Advertising Submissions*

Appreciation to Dr. John O. Godden

This year, at PAAB's Annual Meeting something new will happen for the first time in about two decades. A name will be put in nomination for the position of *Past*-Chair.

Dr. John Godden was first appointed Chairman of PAAB in September of 1978, a logical step for a physician with a solid record in medical publishing, including a period as Associate Editor of the Canadian Medical Association Journal.

Dr. Godden was the third chair in PAAB's first three years. But over the next 19 years his steady hand on the gavel has helped our organization adapt to radical changes facing pharmaceutical advertising.

I am grateful for the guidance and the context that he provided in my early days as Commissioner. Around his kitchen table, I appreciated that this ex-Maritimer could vent equally against firms that might not be taking their self-regulatory responsibilities seriously, and against unnecessary government intervention in day-to-day ad reviews. Plus he continues to be the best text editor any of us have encountered.

Dr. Godden stands for drugs ads that are accurate, balanced, and which represent the best science -- a perspective that PAAB as an organization have adopted as our own. During the year there will be a suitable event in his honour, and we hope to be able to count on access to his expertise and wise counsel.

Which groups make up the "Board" in PAAB?

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

(Health Protection Branch is an ex-officio observer.)