Pharmaceutical Advertising Advisory Board

PAAB 1997 Report

COMMISSIONER'S REPORT

"A breakthrough in reduced turnaround times"

The year 1997 saw a sustained and significant improvement in the efficiency of PAAB's reviewing operations.

PAAB had announced a Service Improvement Initiative in late 1996, starting with a questionnaire to determine user needs. While 98% of PAAB submissions during 1996 were reviewed within the 30-day standard set officially in the PAAB Code, it had become clear that 30 days was no longer quick enough. The survey results gave PAAB good data on firms' recommended solutions.

Part of the solution came from new guidelines to make the reviewing practice clearer. Another part relates to the implementation in 1996 of a "tilted" fee schedule, giving more incentive to advertisers to meet Code standards with their initial submissions and thereby avoiding time-wasting iterations of reviewers' comments and revised ad submissions.

The final step came with the hiring in 1997 of an additional PAAB reviewer, funded by a fee increase of 5 per cent effective July 1 1997. On the same day, the formal turnaround target for initial review of advertising submissions was reduced from 30 calendar days to 10 working days.

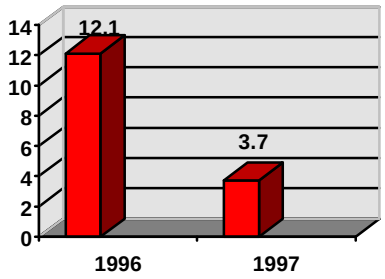
We are glad to report the new review target was met and exceeded throughout 1997.

Detailed data on turnaround performance are found inside this report; no single statistic can fully depict the improvement. However, the *average* number of calendar days elapsed before the initial review of a submission fell from more than 12 days in 1996 to 3.7 days in 1997.

This report was tabled at the PAAB Annual General Meeting on April 8 1998, and is also being distributed more widely in a newsletter format.

Reduced PAAB turnaround times

(Average turnaround to initial review – calendar days)



This report sets out a wide range of activities in which PAAB was involved during 1997 – including complaints resolution, monitoring, 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.

INSIDE

Submission volume continues to climb

A total of 2,535 human pharmaceuticals submissions were reviewed in 1997, up four per cent from 2,435 in the previous year. This increase continues a recent trend, and the 1997 submission volumes represent more than a 12 per cent increase from 1995 levels.

The mix of submissions continues to shift away from single-page journal ads (now comprising about 20% of submissions) towards lengthier detail aids, mailers, audio-visual materials and company-sponsored materials with an educational orientation.

Comparative claims standards set to change in 1998

There was substantial activity in 1997 concerning standards for comparative claims in drug advertising.

The Health Protection Branch released an extensive 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 for health professionals advertising the PAAB is responsible for implementation of the principles.

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 1997, and is proceeding towards revisions to the Code in the coming year.

Until Code revisions are approved by PAAB's Board, comparative claims continue to be reviewed using existing standards, including Section 5 of the PAAB Code and the October 31 1996 PAAB Guideline on the Use of Product Monograph Data in Comparative Claims.

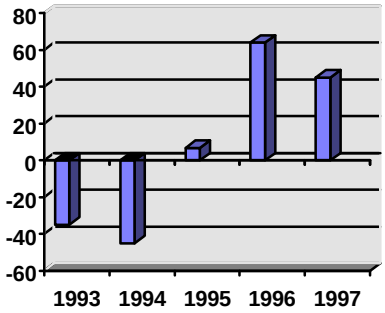
Stable financial picture

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

PAAB achieved an operating surplus of $44,590 during 1997. Revenue during the year reached close to $778,000. Fees were increased by 5 per cent, effective July 1 1997, PAAB's first general increase since 1995. The majority of PAAB 1997 expenditure of $733,000 provides for salaries, including the increased complement of five reviewers.

The 1997 operating surplus helps strengthen PAAB's balance sheet, and the 1998 budget does not project fee increases in the coming year.

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 1997, 87 ads were reviewed, up from 48 in the previous year.

PAAB's arrangement in the veterinary drug field does not involve responsibilities with regard to monitoring. However, PAAB is pleased that the Canadian Animal Health Institute has recently strengthened its Code of Marketing Practices to actively promote preclearance among its members.

PAAB was invited recently by Health Canada to comment on proposals to develop a new regulatory and policy framework for advertising standards for prescription drugs used in animals.

Complaints and monitoring

During 1997, the PAAB Commissioner made 14 complaint rulings. This number contrasts to 29 complaint rulings in 1996, and 43 rulings by the Commissioner in 1995.

During 1997, five of these complaints were 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.

Of the 14 complaints, six were generated from advertising that had been previously PAAB-reviewed; one of these complaints resulted in withdrawal of PAAB's previous acceptance.

- 13 of the complaints were disputes between pharmaceutical companies, many in highly competitive therapeutic categories such as cholesterol-lowering medications and estrogens.
- Three of the complaints concerned OTC products; the remainder were Schedule 1 or 2 (prescription or behind-the-counter).

During 1997, there was a heightened role for PAAB's monitoring program. A total of 67 monitoring letters were sent during the year, notifying advertisers of infractions. Most relate to technical issues of use or printing for materials that had been reviewed and accepted by PAAB.

For example, during 1997, PAAB conducted an initiative to ensure that ads were not used beyond the 12-month period for which PAAB issues acceptances. As a result, 38 monitoring letters were sent about expired ads, and all of these ads were either withdrawn or resubmitted for review.

PAAB regularly monitors journals, the internet, and receives direct-mail/detail aid materials collected by health professionals. During 1997, PAAB pursued several monitoring cases of unreviewed advertising containing misleading or off-label claims, lack of balancing risk/benefit information, or the absence of disclosure of detailed prescribing information; several of these cases were referred to the respective trade associations for appropriate action and/or are reported to the Health Protection Branch as required under the PAAB Code.

Staffing and Training

PAAB's current staff of five professional reviewers is set out below.

In April, **Joanna Rizos** joined our staff. She is a graduate of the University of Toronto faculty of pharmacy, with experience as a community pharmacist. Subsequently, she obtained her MBA as well as a Bachelor of Arts in French translation from York University.

During the year, **Helen Breedon**, reviewer since 1993, moved with her family to Guelph. After some telecommuting, Helen resigned her full-time position. We are pleased that she can still be available for contract reviewing at peak periods. We were also assisted during the summer period by **Sam Kim**, a former reviewer who has returned to university for graduate studies. Reviewer **Jane Shum** is on maternity leave until September 1998.

Near the end of 1997, **John Wong** was hired to join 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.

Our training efforts to upgrade and maintain staff competencies continued in 1997. In addition to individually-directed efforts, all reviewers and the Commissioner participated in a special session on pharmacoeconomics, held in the PAAB offices, led by Professor Tom Einarson of the University of Toronto Faculty of Pharmacy.

During 1997, workshops were held both in Toronto and Montreal for advertisers to widen knowledge on how to prepare submissions that meet the PAAB Code standards.

PAAB staff

Commissioner: Mark McElwain
Deputy Commissioner and Senior Reviewer: 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.

New PAAB Chair, Dr. Reginald Perkin

At its 1997 Annual Meeting, PAAB Directors elected Reginald L. Perkin, MD as PAAB's new Chair.

Dr. Perkin is best known for his role as Executive Director of the College of Family Physicians of Canada from 1985 until his 'retirement' in 1996. A University of Toronto graduate, he practiced family medicine, was head of hospital family practice departments, and was Professor of the UofT Department of Family and Community Medicine.

He brings to the Board of Directors and Executive Committee an excellent scientific background, an awareness of the practicalities of family medicine and strong administrative gifts. He succeeds Dr. John Godden, PAAB Chairman since 1978.

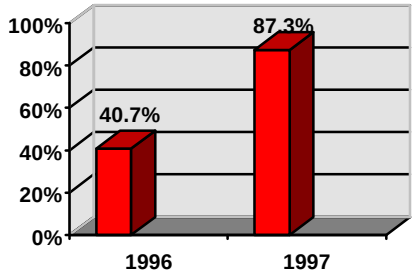
Turnaround details

Each year, we report on key review performance statistics. In the 1996 annual report, we reported that 66% of submissions received initial review within 15 calendar days of arriving at the PAAB office, and 98% met the 30-day performance standard officially set in the PAAB Code.

Using these yardsticks, the 1997 performance improved markedly: 99.3% of submissions were reviewed within 15 calendar days, and 100% met the old 30-day standard.

Below is shown the major improvement in submissions reviewed in five or fewer calendar days; from 40.7% of files in 1996 to 87.3% in 1997.

Share of ads reviewed < 5 days



In 1997, submissions were received on behalf of 102 manufacturers or advertisers, and from a total of 110 advertising agencies.

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 Protection Branch 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 *(including the revised Complaints and Appeals procedures) is also available at:*
http://www.pps.ca/PAAB/home.html

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*

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*