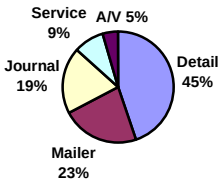
PAAB 1999 Report

COMMISSIONER'S REPORT

Record Number of Advertising Reviews

A total of 2,805 human pharmaceutical product advertising submissions were reviewed in 1999, up 19% from the previous year's 2350. This volume breaks the previous record of 2698 submissions set in 1993.

The mix of submissions was similar to that of 1998. Journal ads comprised 19% of the total, detail aids (45%), mailers (23%), audio-visual materials (5%) and company-sponsored materials with a service orientation (9%). I note that a heavy workload has resulted from the many multi-paged detail aids that can include many references used as substantiation for claims.



In 1999, submissions were received on behalf of eighty-nine (89) manufacturers or advertisers, and from a total of ninety-eight (98) advertising agencies.

Turnaround Time Standard Maintained

During 1999, the PAAB staff maintained the significant improvement in the efficiency of PAAB's reviewing operations that was achieved in 1998.

The staff members met the challenge set by the PAAB Commissioner. One hundred per cent (100%) of initial reviews were completed in 9 working days or less, meeting the Code requirement of ten working days. Ninety-five per cent (95%) of the initial reviews were completed within five working days after receipt of a complete submission.

This record was accomplished despite having fewer Reviewers for most of 1999 as compared to 1998. There was a tremendous surge of reviews in November and December. Record submission review volume was achieved for December and the fourth quarter.

The major factor in achieving this record was having a stable and experienced review staff. There were 4 permanent Reviewers for most of 1999: Senior Reviewer Jane Shum, Colin Campbell, Joanna Rizos and John Wong. Ms. Yin-Ling Man joined the review staff in September 1999.

The review contingent is well supported by

This report, tabled at the PAAB Annual General Meeting on April 28, 2000 sets out a wide range of activities in which PAAB was involved during 1999 – including advertising review, 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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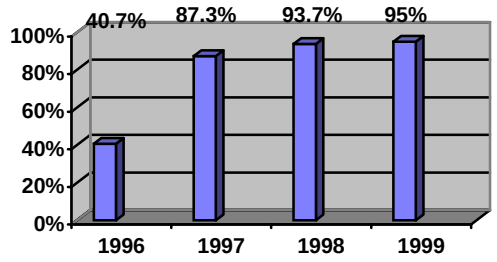
Submission Coordinator Carol Johnston and Receptionist /Secretary Estelle Parkin.

The first review turnaround target of ten working days or less is the PAAB goal for 2000. Shown below is the major improvement in submissions reviewed in five or fewer working days; from 40.7% of files in 1996 to 95% in 1999.

Share of ads reviewed < 6 working days



Code Changes

Comparative claims standards implemented

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 1997 and into 1998.

The revised section helps to clarify what data is required to support comparative claims. Previously, PAAB reviewers' practice had been to require peer-reviewed, head-to-head trials in support of comparative claims of safety and efficacy. This revision codified that practice and helped the Reviewers work with advertisers to improve the quality of comparative advertising.

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.

Commissioner Chepesiuk thanks the industry for their acceptance of the revised section 5 and their cooperation with PAAB Reviewers to effect necessary changes.

Sound Financial Picture

PAAB is a not-for-profit organization that does not receive direct grants from any source. It is solely funded by fees charged to advertisers for the review of advertising submissions.

In 1999 PAAB saw a surplus of $241,000 as compared to -$5,000 in 1998. Revenue during the year was up 26% versus 1998, $961,103 compared to $763,433 in 1998. There was a 5% fee increase in 1999. Operating expenses were down 6%, $719,930 versus $768,061 in 1998. Members equity was increased 88% from $275,588 to $516,136. Contingency investment was increased from $105,433 to $182,403.

There was no apparent explanation for the large submission review volume increase. It was most likely related to the marketing authorization granted to several new products in competitive therapeutic areas. Operating expenses were lower mainly due to decreased staffing in 1999. The 2000 budget is based on no fee increase and a submission review volume that is similar to that of 1998.

New PAAB Commissioner

PAAB Commissioner Mark McElwain resigned his position October 31, 1998. 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. On May 1, 2000 Ray Chepesiuk became the fourth PAAB

Commissioner. Ray had been with PAAB 13 years, and 8 years as Deputy Commissioner. Ray is a Certified Association Executive who has achieved a B.Sc. Pharmacy from the University of Toronto and a Master in International Business from the University of South Carolina. He has held management positions in hospital, community and government pharmacy.

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 1999, 91 ads were reviewed, a similar number to the 86 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

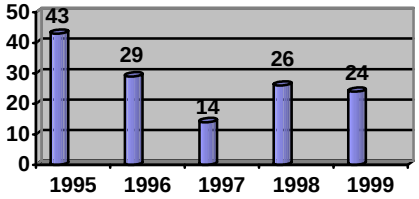
During 1999, the PAAB Commissioner processed 24 Stage 2 **complaints**. This number was similar to the 26 complaint rulings in 1998.

Of the 24 complaints, 16 were generated from advertising that had been previously PAAB-reviewed; 11 of these complaints resulted in withdrawal of PAAB's previous acceptance (PAAB reviewed 2805 advertising pieces in 1999). Five complaints were rejected. Of the 8 complaints on advertising that was not PAAB-approved, 7 were sustained. Two 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. PAAB referred two complaints involving pre-NOC issues to Health Canada.

- 20 of the Stage 2 complaints were disputes between pharmaceutical companies. Four complaints were received from health professionals.
- 4 of the complaints concerned nonprescription products (4 were sustained); the remainder were Schedule F Part 1 (prescription drugs) and four biological products.
- 17 of the 24 complaints were for new products less than two years on the market.
- 11of the 18 complaints that were sustained involved comparative claims.
- 11 of the complaints that were sustained involved primarily journal ads; 6 detail aids and 5 mailers.

Most sustained cases concluded with withdrawal of material as a penalty and referral to trade industry associations (where applicable) for further assessment of monetary penalties. Two were referred to Health Canada for assessment.

Stage 2 Complaints



There was one stage 3 panel hearing that resulted in one allegation being sustained and one allegation being rejected.

During 1999, 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 22 (compared to 16 in 1998) 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. When warranted, cases are referred to the respective trade associations for appropriate action and/or reported to Health Canada in cases dealing with pre-Notice of Compliance or public safety issues.

DTCA activities

During 1999, Commissioner Chepesiuk was involved in several activities relating to Direct-to-Consumer advertising of prescription medicines. By invitation, 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. When requested, the Commissioner intervened on complaints involving DTC material.

Staffing and Training

PAAB's current staff of four professional reviewers are listed below.

Our training efforts to upgrade and maintain staff competencies continued in 1999. PAAB supported individual self-learning efforts and attendance at conferences. PAAB reviewers have been hosted by manufacturers and advertising agencies for drug advertising and marketing orientation sessions.

In 1999, in agreement with Parke-Davis, for the first time PAAB reviewers accompanied manufacturer representatives on their routine sales calls on doctors for one day.

The staff participated in a workshop on critical appraisal of scientific studies held by two professors in epidemiology from the University of Western Ontario. Planning was begun for a March 2000 PAAB reviewer training program in conjunction with an expert in critical evaluation of medical literature involving statistical issues from the University of Toronto.

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

Outlook 2000

At the beginning of 2000, I identified three personal organizational objectives, keeping in mind the PAAB mission. First, I will strive to improve the quality of PAAB reviews by a number of mechanisms. I will support and encourage the Reviewers to conduct reviews that are reproducible, professionally communicated and that ensure advertising meets the PAAB Code standards for accuracy, balance and evidence-based. I will support Reviewer training and implement access to e-mail and the Internet. I will formalize PAAB policies requiring consultation among Reviewers before certain review letters can be sent. I will initiate Code revisions or guidelines to provide transparency of the review process.

Second, I will maintain and consolidate the review turnaround time efficiency by supporting the Reviewers to achieve goals of 100% of initial reviews within the Code standard of ten working days and 90% within 5 working days.

Third, I will strive to raise the profile of PAAB with Industry and external stakeholders by continuing submitter training presentations, enhancing the PAAB Web-site to include relevant and useful information, implementing a journal ad campaign and working with the Board to attract new member organizations that have an interest in the regulation of drug advertising.

I want our client stakeholders to believe that PAAB is approachable, decisive and fair in its administration of the preclearance review mechanism. I want our external stakeholders to believe that PAAB preclearance review mechanism is open, flexible and of high quality.

For more information on PAAB, see
www.paab.ca

PAAB staff

Commissioner:	Ray Chepesiuk
Senior Reviewer:	Jane Shum
Reviewers/Assistant Commissioners:	Colin Campbell John Wong Yin-Ling Man
Submission Co-ordinator:	Carol Johnston
Administrative Support:	Estelle Parkin
Accounts:	Glenn Golaz

All can be reached at 905-509-2275