Pharmaceutical Advertising Advisory Board **October 1999**

PAAB UPDATE

PAAB
ACTIVITIES DURING THE
THIRD QUARTER OF 1999

Ad hoc DTC Committee formed

At the June 22 1999 Executive Committee meeting, Dr. Reg Perkin created a sub-committee to analyze PAAB's operational readiness to handle Direct-to-Consumer prescription advertising and to make recommendations to the Board. David Skinner (NDMAC) was appointed Chair and the members are Jean Jones. (CAC), Edward Stapor (AMAA), Dr. Perkin, Faheem Hasnain (Rx&D Canada) and Commissioner Ray Chepesiuk. The first meeting was held September 8 and it is expected that the Committee will make recommendations to the Board at the November General Meeting.

New Reviewer Hired

Commissioner Ray Chepesiuk is pleased to announce that PAAB has hired a new Assistant Commissioner/Reviewer, Ms. Yin-Ling Man, effective September 7, 1999. Yin-Ling is a graduate of the University of Toronto and has been a practicing hospital and community pharmacist in Toronto. She becomes the fifth reviewer in the current PAAB staff. PAAB had been handling the increased 1999 volume with four reviewers, one less than the staff complement during most of 1998. Yin-Ling will be trained under the supervision of Senior Reviewer Jane Shum.

November General Meeting

The next PAAB General Meeting of Directors will be held Friday November 5, 1999 at the College of Family Physicians in Mississauga, Ontario from 9 a.m. to 1 p.m.

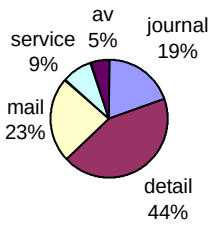
Code Clarification Bulletins

In early October, 2400 Canadian drug marketers received two bulletins from PAAB. One clarified the Code section 7 requirement for prescribing information to accompany direct mail (including Fax) advertising. The other guideline clarified the application of the Code section 6.6a re educational material exemptions from PAAB review. The clarification bulletins were distributed because the PAAB staff noticed a rise in Code infractions in these activities.

Review Activity

During the period of July 1 to September 30 1999, the total number of submissions reviewed was 683. This compared to 592 during the same period of 1998, a 15% increase.

The proportion of advertising vehicles that were submitted for review shows a workload oriented



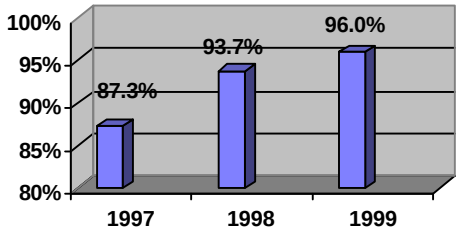
towards detail and direct mail activity.

In 1999, the total number of submissions reviewed year-to-date was 2040, an 18% increase compared to the 1998 total of 1721.

During the third quarter of 1999, 91% of the submissions were given a first review response in five days or less and 100% were given a review response in 8 days or less.

For year to date, 96%% were reviewed in 5 days or less and 100% in 9 days or less.

Share of ads reviewed in 1- 5 days



COMPLAINTS AND MONITORING

PROCESS

Complaints against Advertising/Promotion Systems (APS) may be lodged by: health professionals, health care organizations, pharmaceutical companies, federal and provincial regulatory bodies and drug payer organizations.

Code Section 9 contains a guide for the resolution of complaints against pharmaceutical advertising that is subject to review by the PAAB. Organizations are encouraged to act in the spirit of the Code to seek resolution and abide by those terms, even in specific situations which are not directly anticipated in section 9.

There are three different levels of PAAB administrative response. In **Stage ONE***, the complaint is sent directly to the advertiser by the complainant or to the advertiser via the PAAB Commissioner. The advertisers responds in writing to the complainant. The complainant then has three options: continue discussion with the advertiser, possibly by writing another letter narrowing the points of dispute; accept the advertiser's response; or conclude that further intercompany dialogue will not be productive and therefore seek review by the PAAB Commissioner in* **Stage TWO***. Either the complainant or advertiser has the right to appeal the Commissioner's reassessment ruling to a* **Stage Three** *independent Review Panel made up of three qualified individuals selected by the Commissioner from individuals named by national organizations.*

PAAB COMPLAINT REPORT
Period: July 1, 1999 to September 30, 1999

During the period of July 1 to September 30 1999, the PAAB Commissioner processed 8 **Stage 2 complaints**. This number brings the total for 1999 to 17. PAAB reviewed 682 advertising pieces during the months of July, August and September 1999 and the year-to-date total is 2040.

Of the 8 complaints, 4 were generated from advertising that had been previously PAAB-reviewed with two having the same advertising as the subject. All 4 of these complaints resulted in withdrawal of PAAB's previous acceptance. One of these complaints was sent to PAAB by a group of health professionals. The 4 complaints on advertising that were not PAAB-approved were sustained. Two were sent to PAAB by health professionals. One of those complaints was sent to Health Canada for action because it related to a product that had not received Notice of Compliance in Canada.

PAAB has continued to regularly **monitor** journals, the Internet, and receive direct-mail/detail aid materials collected by health professionals as part of its monitoring program. During the third quarter of 1999, a total of 5 monitoring letters were sent for 2 unreviewed pieces containing misleading and/or off-label claims and 3 expired ads. This brings the total for this year to 19. All of the ads were either withdrawn or resubmitted for PAAB review. Two cases were referred to their respective trade association for appropriate action while in one case Health Canada was informed of the infraction.

STAGE TWO DECISIONS

1.

ADVERTISER: AstraZeneca

COMPLAINANT: Bristol-Myers Squibb & Sanofi

SUBJECT: c99-18 Atacand (candesartan) PAAB-approved Detail Aid and Journal Ad approved in 1998. See also #3 re c99-28

PRECLEARANCE: Yes

ALLEGATIONS: multiple allegations citing 21 Code sections. Two allegations were sustained . These two were similar to the two allegations sustained in the complaint ruling on Atacand file c99-28.

PAAB DECISION: Sustained part of allegations, rejected others. Violation of section 3.1; although AstraZeneca argues that showing the 32 mg dose was necessary to prove dose-

response, promotion of the 32 mg dose is not accepted because it is not an approved dose within the Health Canada accepted Product Monograph. Violation of section 5.2 which came into effect January 1999; comparison of Atacand 16 mg versus Cozaar 50 mg and related superiority claims is an unfair comparison of non-equivalent doses. The other allegations were rejected because they were subjective in nature and did not have substantive merit.

PENALTY: AstraZeneca had already responded to the previous ruling on c99-28 and had discontinued distribution of the offensive materials. New material had been created to replace the violative material. Therefore, no additional penalty was assessed.

OUTCOME: AstraZeneca complied with ruling and revised their advertising material. PAAB reviewers were informed of the ruling.

2.

ADVERTISER: Eli Lilly

COMPLAINANT: 3 Health Professionals at British Columbia Ministry of Health and University of British Columbia.

SUBJECT: c99-24 Evista (raloxifene) Journal ad, PAAB-approved in 1998.

PRECLEARANCE: Yes (1998)

ALLEGATIONS: Allegations related to improper prescribing information, promotion of unapproved indications, misleading claims, and omission of clinically significant risk information.

PAAB DECISION: Sustained part of complaint allegations, rejected others. There appeared to be infractions of Code sections 2.1 and 3.1. With respect to the copy and graphics, PAAB agreed with the complainant that the context of the ad, i.e. position of copy and graphics, use of small type size footnotes for safety information, was found to be misleading because it did not appropriately reflect the spirit and context of the related claims in the product monograph. There is a perception of promotion of unapproved indications under a general headline stating "woman's health" as opposed to "osteoporosis". Wording related to "choice" was ambiguous and could give the impression that Evista was "the first choice" (code section 5.15). A safety claim related to venous thromboembolic events should be conveyed in advertising. To address Code section 4.2 absolute values should accompany relative risk values to clarify the meaning. The allegations about improper prescribing information were rejected. PAAB advised Eli Lilly that a Detail Aid containing a similar context should be revised.

PENALTY: Eli Lilly was ordered to discontinue future insertions of the journal ad and destroy the current detail aid. PAAB would work with Eli Lilly to expedite revised material for earliest distribution.

OUTCOME: Eli Lilly agreed with the PAAB ruling and met with PAAB to discuss revision. Eli Lilly chose not to advertise by journal ad during the remainder of 1999 and the detail aid was revised during the month of August 1999.

3.

ADVERTISER: AstraZeneca

COMPLAINANT: Merck-Frosst

SUBJECT: c99-28 Atacand (candesartan) PAAB-approved Detail Aids approved in 1998. See also #1 re c99-18.

PRECLEARANCE: Yes

ALLEGATIONS: Promotion of 32 mg dose that is not consistent with the Product Monograph. Unfair comparison of Atacand 16 mg to Cozaar 50 mg, (s5.2).

PAAB DECISION: Violation of section 3.1; although AstraZeneca argues that showing the 32 mg dose was necessary to prove dose-response, promotion of the 32 mg dose is not accepted because it is not an approved dose within the Health Canada accepted Product Monograph. Violation of section 5.2 which came into effect January 1999; comparison of Atacand 16 mg versus Cozaar 50 mg and related superiority claims constitute an unfair comparison of non-equivalent doses.

PENALTY: Discontinuation of both detail aids.

OUTCOME: AstraZeneca agreed with the PAAB decision.

4.

ADVERTISER: AstraZeneca

COMPLAINANT: Abbott

SUBJECT: c99-33 Losec journal ads

PRECLEARANCE: No

ALLEGATIONS: Abbott states that AstraZeneca "knowingly and willingly" omitted prescribing information from journal ads to save money and gain a competitive advantage.

PAAB DECISION: Upon investigation, it was learned that the advertising agency for AstraZeneca took responsibility for the omission. Early insertions were accompanied by Prescribing Information and another ad with multiple claims. The agency thought the minor claim structure of the journal ad warranted Reminder Disclosure after the multiple claim ad stopped running. PAAB had approved the ad to run with

prescribing information. PAAB could find no evidence that AstraZeneca willfully propagated this action to gain a competitive advantage.

PENALTY: AstraZeneca to include prescribing information and consult PAAB in future regarding reminder disclosure requirements.

OUTCOME: AstraZeneca agreed with the PAAB decision.

5.

ADVERTISER: Glaxo Wellcome

COMPLAINANT: Hoechst Marion Roussel

SUBJECT: c99-35 Zyban (bupropion) PAAB-approved journal ad.

PRECLEARANCE: Yes

ALLEGATIONS: There is misleading wording on a comparative claim in that the specific comparative agent was not stated in body copy, but only in a footnote. The claim "compared to the patch" implied a broader comparison that was not substantiated.

PAAB DECISION: Although not grossly misleading, the ad should be revised to state the comparative agent in a clear manner to meet the current requirements of Code sections 2.1 and 5.5.

PENALTY: Withdrawal of PAAB acceptance and creation of a new journal ad.

OUTCOME: Glaxo Wellcome agreed with the PAAB decision.

6.

ADVERTISER: Ferring

COMPLAINANT: c99-38 - Health professional at Dalhousie University and forwarded by Health Canada

SUBJECT: Non-PAAB approved Journal ad with PAAB Clearance having expired in January 1998.

PRECLEARANCE: No (Expired January 1998)

ALLEGATIONS: Alleges wording "end bedwetting" is not supported by the listed reference i.e. there is no support for a claim of long term or absolute end to bedwetting. Company responds that more data will appear from ongoing trials to support the claim.

PAAB DECISION: Commissioner rules that claim is premature because the short term methodology of the support study does not support an absolute claim of "end bedwetting". Ad should be revised. Also, there is an infraction of advertising without current PAAB clearance.

PENALTY: Discontinue ad immediately and revise claims for a new ad.

OUTCOME: Ferring agrees with PAAB decision.

7.

ADVERTISER: Maxima Pharmaceuticals

COMPLAINANT: Health professional in Winnipeg and referred by Rx & D Canada..

SUBJECT: c99-41 multi-product Diffusimax mailer

PRECLEARANCE: No.

ALLEGATIONS: Promotion of products prior to obtaining Notice of Compliance from Health Canada.

PAAB DECISION: In accordance with bi-partite agreement about off-label claims (pre-NOC advertising), this complaint was forwarded to Health Canada for action.

PENALTY: Awaits Health Canada decision.

OUTCOME: Awaits Health Canada decision.

8.

ADVERTISER: Hoechst Marion Roussel

COMPLAINANT: Pfizer Canada

SUBJECT: c99-41 Allegra (fexofenadine) detail brochure

PRECLEARANCE: No

ALLEGATIONS: The context of the graphic depicting a sleeping person beside first generation antihistamines and Reactine (cetirizine) was an unfair attack (s5.6).

PAAB DECISION: The brochure was similar in content to a brochure approved by PAAB. However, a graphic depicting a sleeping person was added to two places and this was not brought to the attention of PAAB. The Commissioner ruled that the graphic comparison was an unfair attack because the comparative claim contradicted the the Health Canada approved product monograph for Reactine.

PENALTY:

1. HMR to immediately discontinue distribution and promotion of the brochure.

2. HMR to recall and destroy all distributed brochures.
3. HMR to send letter to pharmacists to explain the recall of the brochures.

OUTCOME: HMR agreed to carry out the prescribed action by September 15, 1999.

PAAB staff

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

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

Who makes up the "Board" in PAAB?

Voting Organizations

Advertising Standards Canada
Association des médecins de langue française du Canada
Association of Medical Advertising Agencies
Canada's Research-Based Pharmaceutical Companies
Canadian Association of Medical Publishers
Canadian Drug Manufacturers Association
Canadian Medical Association
Canadian Pharmacists Association
Consumers' Association of Canada
Nonprescription Drug Manufacturers Association

Voting Individuals

Chair Dr. R. Perkin
Past Chair Dr. J. Godden

Health Canada is an ex-officio observer

Executive Committee

Chair Dr. Reg Perkin

Vice-Chair Edward Stapor

Treasurer Phil Diamond

Member Gloria Bowes

Member vacant

Commissioner Ray Chepesiuk

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.

Key activities of PAAB include:

- *Maintaining the Code of Advertising Acceptance, which is approved by representatives of member organizations*
- *Preclearing advertising prior to publication, to ensure claims meet Code standards. The scope of the Code currently includes advertising of prescription and OTC drug products to health professionals, in all media. PAAB also reviews veterinary medicine journal advertising using separate guidelines*
- *Training, adjudicating complaints, administering penalties, reporting of infractions, and other activities to encourage compliance.*

For information or if you have comments:

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The PAAB Code of Advertising Acceptance and PAAB Supplementary Guidelines are available from the PAAB office or at www.paab.ca

You can find these key Health Canada documents at http://www.hc-sc.gc.ca/hpb- dgps/therapeut/htmleng /policy.html

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