Pharmaceutical Advertising Advisory Board **January 2000**

PAAB UPDATE

Quarterly Information Bulletin

PAAB
ACTIVITIES DURING THE
FOURTH QUARTER OF 1999

Year 2000 marks the 24th operating year of drug advertising review for PAAB since its incorporation in 1976. You can get this document in French from the PAAB office or see it on the PAAB Web-site. To see the current edition of the PAAB Code, visit the PAAB Web-site

www.paab.ca

Ce document est également disponible en français au bureau du CCPP ou sur notre site web.

Code Changes Approved by Board

The most recent PAAB General Meeting of Directors was held Friday, November 5, 1999 at the College of Family Physicians in Mississauga, Ontario. The next Annual / General Meeting will be held on April 28, 2000 from 9 a.m. to 1 p.m. at the same location.

At the November 5, 1999 General Meeting, The PAAB members approved the following Code and Explanatory Note changes:

Add Explanatory Note 4.2.3

Reporting clinical trial results in relative or proportional terms may lead to misinterpretation of the true benefit and degree of a treatment effect. APS which present results using these methods of reporting, namely relative risk (RR) or relative risk reduction (RRR), must also include an indication of the absolute treatment effect. This can be presented as absolute risk reduction (ARR), number needed to treat (NNT) and/or the actual comparative clinical results or rates. The overall presentation should reflect the true magnitude of benefit and not magnify the clinical effect. Undue emphasis on treatment effects in relative terms, by means of graphic presentation or differences in type size, is not acceptable.

Addition of fourth paragraph – Code Section 6.1

Each discrete advertisement in a publication must satisfy PAAB Code requirements.

Add Explanatory Note 6.1.3

Advertisements that are displayed in multiple portions over contiguous pages (e.g. over pages 3, 5, and 7) may be deemed to be a single advertisement and reviewed as such provided each part can be easily identified as part of the complete ad.

Portions of advertisements that will not be displayed on contiguous pages will be reviewed as discrete advertisements. The advertiser must inform PAAB if ad portions will not appear contiguously.

Revise Code section 9.7.6

Change "… to pay $2500 in costs for the review panel and preparations" to read "… to pay $2500 plus actual costs for the review panel and preparation."

Revise Code section 9.8.4

Change " the appellant company is liable to pay costs up to $1500." To read " … the appellant company is liable to pay $2500 plus actual costs."

Revise Code section 6.5

In the second paragraph change "… slides and film." To read " … slides, film and television."

Add Code section 7.9

Electronic Broadcast Media Disclosure prescribing information must include a full screen graphic extending a minimum of 10 seconds in length appearing at the end of the advertising presentation. The graphic should include the following:

a) A statement that the product monograph is available on request from the company name, postal address and e-mail address and telephone number and fax number;

b) A statement concerning major restrictions in usage and distribution, when required by the product monograph including boxed or bold copy;

c) Any major labeling contraindications, warnings and precautions required by the product monograph including boxed or bold copy.

Look for the New PAAB Logo

The PAAB members have approved a new logo to distinguish Canadian drug advertising that has been reviewed by PAAB. Check our Web-site to get the new look logo. Also, call the PAAB office for facsimiles. To encourage health professionals to look for the PAAB logo on advertising, the Canadian Association of Medical Publishers has agreed to run PAAB journal ads bringing attention to the PAAB Web-site as a source of information about drug advertising regulation.

Television Advertising Review

In 2000, PAAB is looking forward to reviewing television advertising directed at physicians via HealthSat Network. Presentations will include weekly programs created by such groups as Rural, Emergency, University and Royal College specialty societies. Regular medical news will provide updates on national and global current affairs. Live and pre-recorded programming will feature general interest topics such as practice management, legal, ethical debates and financial planning.

Clarification on Reminder Category Prescribing Information Requirements

Code section 7.6 outlines the requirements for *Reminder* category advertisements. This type of message is designed to allow companies to keep the identity and therapeutic purpose of their pharmaceutical products before the health professions. This category allows for minimal prescribing information requirements and it may replace Full Disclosure advertising only under specific conditions as outlined in the Code. The main condition is that there are no advertising claims either in text or in graphics, including logos.

PAAB has noticed a recent trend for companies to publish Reminder ads that have neither been reviewed by PAAB nor did they meet the requirements of the PAAB Code. In particular, some ads have included taglines with efficacy, safety, status or merit claims that were approved by PAAB to appear in Full Disclosure or Condensed Disclosure advertising. However, prescribing information was not included. Advertisers have also included logos with graphics that depict a claim e.g. mechanism of action, protective effect.

The PAAB Commissioner reminds all advertisers that the above examples are infractions of the PAAB Code and possibly the Food & Drugs Act. All Reminder ads should be submitted to PAAB for preclearance review. See Code section 6.1.3.

Internet Advertising

The Commissioner is frequently asked if the PAAB Code covers Internet advertising. This is a reminder that pharmaceutical product advertising intended for health professionals and placed on Internet Web-sites that originate in Canada are subject to the PAAB Code of Advertising Acceptance.

Pay Your Bill Promptly

During the review of the 2000 PAAB budget, PAAB Members expressed concern about the large amounts of money owed to PAAB past 30 days. PAAB is funded entirely by the fees paid for the review of advertising. The invoice is sent within a week after the first review. Therefore, we ask the PAAB clients to ensure that the PAAB invoice is paid promptly on receipt. The Members directed the Commissioner to refuse the review of advertising for delinquent clients.

Review Activity

The last quarter saw a large volume of review activity with the majority of the submissions coming in November and December.

During the period of October 1 to December 31 1999, the total number of submissions reviewed was 764. This compared to 633 during the same period of 1998, a 21% increase.

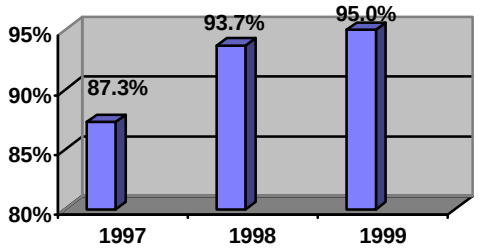
The proportion of advertising vehicles that were submitted for review shows a heavy workload oriented towards detail aid activity (49%).

In 1999, the total number of submissions reviewed was 2805, a 19% increase compared to the 1998 total of 2354.

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 first review response in 8 days or less.

For the year, 95%% were given a first review response in 5 days or less and 100% in 9 days or less. *This meets the Code requirement of ten days for a first review response.*

Share of ads with first review 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: October 1, 1999 to December 31, 1999

During the period of October 1 to December 31, 1999, the PAAB Commissioner processed 7 **Stage 2 complaints**. This number brings the total for 1999 to 24. PAAB reviewed 777 advertising pieces during the same period and the year total is 2818.

Of the 7 complaints, 2 were generated from advertising that had been previously PAAB-reviewed. All 2 of these complaints resulted in withdrawal of PAAB's previous acceptance. One of these complaints was sent to PAAB by a physician. The 5 complaints on advertising that were not PAAB-approved were sustained. Two complaints were sent to Health Canada for action because they related to a product that had not received Notice of Compliance in Canada.

In addition, 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. When Code violations are discovered, PAAB sends a letter to the advertiser seeking their cooperation to meet the requirements of the Code. When appropriate, PAAB will notify the advertisers trade association and/or Health Canada for their assessment of additional penalties. PAAB sent 5 notice of violation letters in the fourth quarter.

STAGE TWO DECISIONS

1.

ADVERTISER: Bristol-Myers Squibb

COMPLAINANT: Merck Frosst

SUBJECT: c99-34 Avapro Journal Ad

PRECLEARANCE: Yes

ALLEGATIONS: Claim of "more effective at starting dose" was challenged by Merck Frosst because they claimed that the Oparil study was not sufficient

evidence. There was statistically significant differences at only two of the four endpoints and there was no difference in normalization and responder rates. (See s5.5 iii – appropriate interpretation of data).

PAAB DECISION: There was some confusion and disagreement about the primary end-point of the study. However, the Commissioner believed there was not sufficient evidence to support such an unrestricted claim. Past files revealed that the claim had evolved out of the context of a restricted claim.
PENALTY: Cease distribution immediately and provide a an insertion list of past insertions.

OUTCOME: BMS agreed and ad was stopped as of December 1999.

2.
ADVERTISER: Maxima

COMPLAINANT: Manitoba physician specialist and forwarded by Rx&D.

SUBJECT: c99-39 Diffusimax mailed multi-product brochure

PRECLEARANCE: No

ALLEGATIONS: Violation of Food & Drugs Act i.e. Promotion of products that have not received marketing approval by Health Canada. (See s3.1 claims must be consistent with labeling approved by Health Canada.)

PAAB DECISION: In accordance with Health Canada policy, referred to Health Canada for enforcement action. See also c99-44.

3.
ADVERTISER: Schering

COMPLAINANT: Rhone-Poulenc Rorer

SUBJECT: c99-43 Nasonex detail aid

PRECLEARANCE: No (although the detail aid was PAAB approved, it was distributed with another APS to which a representative applied a non-approved sticker with superiority claims)

ALLEGATIONS: misleading superiority comparative bioavailability claim "lowest systemic bioavailability" based on data for nasal bioavailability versus oral bioavailability (s5.2 comparison made under same conditions of use and no clinical significance must be stated or implied where none has been proven); and misleading price comparison "Lower Price vs other Nasal Steroids" because unit of comparison was a package unit, making evaluation of the claim difficult.
PAAB DECISION: Presentation was factual but the context was potentially misleading, more so when the sticker with the overt claim was attached to the promotional material. Section 5.2 requires that clinical significance be established before a statement can be made. In this case, authoritative comparative data was not available.

PENALTY: Schering to cease distribution immediately and destroy all outstanding copies.

OUTCOME: Schering agreed with the ruling.

4.
ADVERTISER: Maxima

COMPLAINANT: Dimethaid

SUBJECT: c99-44 Diffusimax multi product brochure

PRECLEARANCE: No

ALLEGATIONS: multi-product brochure is a violation of Food & Drugs Act i.e. Promotion of products that have not received marketing approval by Health Canada. (See s3.1 claims must be consistent with labeling approved by Health Canada.)

PAAB DECISION: In accordance with Health Canada policy, referred to Health Canada for enforcement action. See also c99-39.

5.
ADVERTISER: Smith & Nephew

COMPLAINANT: Convatec
SUBJECT: c99-53 Flamazine journal ad

PRECLEARANCE: No

ALLEGATIONS: This ad was in the context of a 47 word section of a two page spread providing claims for medical devices. Ten allegations involving non approved indications (s2.1, 3.1), missing non-proprietary

name (s2.2), no prescribing information (s7.3), no safety balance (s2.4, 3.5), data on file as evidence (s5.8), unstated comparative agents (s5.6), lack of evidence for efficacy claims (s3.4), superiority claims (s5.7, 5.15).

PAAB DECISION: Contraventions: (1) s6.1 requirement for journal ads to be submitted to PAAB for review. (2) s7.3 requirement for condensed disclosure prescribing information to accompany advertising with claims. (3) s2.2 requirement for non-proprietary name (4) s2.4 requirement for appropriate risk to benefit balance (5) s5.7 requirement for substantiation of superiority claims.

PENALTY: It appeared that Smith & Nephew employees were not familiar with the PAAB self-regulation process. PAAB had no record of clearing any ads for Smith & Nephew and requested them to cease distribution of the ad and send it to PAAB for review prior to further distribution. PAAB explained self-regulation mechanism and advised that lack of compliance with PAAB leads to the file being referred to Health Canada for review.

OUTCOME: Smith & Nephew agreed to cease distribution and comply with PAAB self-regulation process in the future.

6.
ADVERTISER: Bristol-Myers Squibb

COMPLAINANT: Merck Frosst

SUBJECT: c99-55 mailer, unpublished article deemed to be promoting Avapro (irbesartan), written by a single doctor and commissioned by BMS.

PRECLEARANCE: No

ALLEGATIONS: Article titled "Angiotensin II AT_1 Receptor Blockers" is advertising and not exempt from PAAB review. Article contains misleading claims that were the subject of other complaints about Avapro APS.

PAAB DECISION: BMS claimed section 6.6.a exemption for independently produced material. This was not an independent meeting report, or accredited CME. Creation of the article by a writer hired by BMS through its agent publisher does not meet the requirements for a section 6.6.a exemption from PAAB review.
PENALTY: BMS to cease unsolicited distribution.

OUTCOME: BMS agrees to cease distribution and states that there was a one-time mailing.

7.
ADVERTISER: Eli Lilly

COMPLAINANT: Novo Nordisk

SUBJECT: c99-58 Humalog detail aid and patient pamphlet

PRECLEARANCE: Detail Aid Yes; Pamphlet No

ALLEGATIONS: **1)** Claim of "less hypoglycemia than 30/70" was not proven (s5.5 insufficient data) because it was not supported directly by the product monograph and the published study provided by Lilly was contradicted by newer published data. **2**) Claim of "proven superior postprandial control compared with 30/70" was not proven (s5.5 insufficient data) because it was not supported directly by the product monograph. **3)** Claim "A simple dose for dose switch from 30/70" is misleading and misrepresents labeling. **4)** patient pamphlet has claim of dosing timing that is unfair attack on Novo Nordisk products.

PAAB DECISION: **1)** The claim "less hypoglycemia than 30/70" was originally approved by PAAB in December 1998 based on the support of one study that appeared to be consistent with the extrapolation of claims for Humalog in the approved product monograph. Subsequent to PAAB approval, Novo Nordisk sent a new study to PAAB that presented conflicting results. Therefore, PAAB ruled that extrapolation was premature at this point and more data would be need to support that claim. A claim re nocturnal hypoglycemia appears to be supportable by sufficient evidence. **2**) Allegation rejected because product monograph does support the claim "proven superior postprandial control compared with 30/70". **3)** Allegation rejected because the claim is consistent with the product monograph direction "use the same dose and dosing schedule" and it is accompanied by an appropriate note of caution about switching. **4)** Allegation rejected because **t**he PAAB Code does not require the review of patient pamphlets and the claim appears to be a reasonable reflection of the relevant product monographs.

PENALTY: Revise materials to remove the claim "reduced hypoglycemia compared with 30/70.

OUTCOME: Eli Lilly agreed with the PAAB ruling and will revise all materials that contain this claim within the agreed time frame.

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
Treasurer Phil Diamond

Health Canada is an ex-officio observer

PAAB Executive Committee

Chair Dr. Reg Perkin
Vice-Chair Edward Stapor
Treasurer Phil Diamond
Member Gloria Bowes
Member John Suk
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*

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