

PAAB UPDATE

Quarterly Information Bulletin

PAAB ACTIVITIES DURING THE SECOND QUARTER OF 2000

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.

New Code Look

PAAB has reprinted the Code of Advertising Acceptance. The 'new look' code book incorporates the new PAAB logo unveiled in 2000. The April 28, 2000 version of the Code captures all of the revisions to the Code passed by the PAAB members since July 1999. A copy of the new code book was distributed with this July PAAB UPDATE to all of PAAB's clients. Additional copies can be purchased from the PAAB office for \$4.00 each. Alternatively, you can download the entire text of the Code from the PAAB Web-site.

Annual/General Meeting

The PAAB Annual/General Meeting of Directors was held Friday, April 28, 2000 at the College of Family Physicians in Mississauga, Ontario. The

next General Meeting will be held on November 10, 2000 from 9 a.m. to 1 p.m. at the same location.

- The PAAB members voted to revoke the membership of L'Association des médecins de langue française du Canada. The association had not participated in PAAB meetings during the past 5 years and it had not responded to correspondence about their membership.
- Mr. James Dunsmuir attended as an Observer from the Canadian Association of Retired Persons (CARP).
- The members approved revision of PAAB Code sections 7.8 and 7.8.1 to clarify that pre-NOC advertising teaser ads are subject to PAAB preclearance review and that pre-NOC product promotion is not acceptable.



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DTCRx Advisory Service

We remind you that PAAB will give an advisory opinion on specific projects that involve information directed at the general public. Currently, companies cannot advertise prescription drugs or treatments of schedule A diseases to the general public. We can assist you in interpreting Health Canada guidelines on what is advertising and what is not considered to be advertising. PAAB will charge its regular review fee for written opinions.

Internet Advertising Guidance

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 or are controlled by Canadian pharmaceutical companies** are subject to the PAAB Code of Advertising Acceptance. In fact, if it is *advertising*, it is subject to the Food & Drugs Act and Regulations.

To determine if it is subject to PAAB preclearance review, you should determine the following:

- Is the message directed to health professionals?
- Is it a message about the company's products, mentioning brand names or non-proprietary names?
- Is the insertion of the message paid by the manufacturer or distributor of the drug product?

If the answers are yes, it is advertising subject to PAAB review and it should be submitted to PAAB in the usual manner for preclearance review.

If the information is directed to the general public, then you must remember the requirements of the Food & Drugs Act. You cannot promote the sale of a prescription drug or a treatment of a disease listed in Schedule A of the Act. You should consult the Health Canada guideline, *The Distinction of Advertising and Other Activities*.

If the information is directed to health professionals, you should make that intent obvious by:

- Using passwords to protect the site or the portion of the site directed to practitioners
- Making the content of the site obviously directed to health professionals as demonstrated by subject matter and terminology
- Not providing key words for search engines that appear to attract the general public to your site
- Not promoting the site in any manner to the general public

You can provide links to other sites provided it does not appear that you are promoting the sale of a Schedule F Drug e.g. "for U.S. Company X Web-site click here" as opposed to "for information on brand X click here".

Fair Balance

PAAB has published and distributed several notices about the requirements of PAAB Code sections 2.1, 2.4 and 3.5. We thank advertisers for their cooperation with the PAAB reviewers and their understanding that the PAAB requirement for balanced information is consistent with the requirement in federal law. Health Canada has been monitoring drug advertising for that requirement and has sent specific complaints and a request for action by PAAB.

“Natural Source” Claims

PAAB has sent an advisory to distributors of estrogen replacement therapy (ERT) products advising them of potentially misleading “natural source claims” based on the interpretation of the Health Canada guideline. A copy of the PAAB advisory and the Health Canada guideline can be obtained from the PAAB office.

New PAAB Staff

We welcome two new Reviewers to the PAAB office. **Lucia Kim** has a B.Sc.Phm from the

University of Toronto. Lucia has experience in the pharmaceutical industry in medical information and government affairs. She also has experience as a community pharmacist. **Pauline Dong** has a B.Sc. Pharm from the University of Toronto and has experience as a community pharmacist.

Misleading Class Claims

Health Canada has advised PAAB not to accept claims that may appear for a class of drugs in consensus guidelines and published literature but do not appear in the Product Monograph for individual products. Examples are mortality claims for lipid lowering drugs, cardiovascular claims for estrogen replacement drugs, end-organ protection claims for anti-hypertensive agents. PAAB Reviewers will be enforcing this requirement as seen in PAAB Code section 3.1. PAAB asks all advertisers to consider this advisement during the planning stages of their advertising creation process.

Review Activity

During the period of April 1 to June 30, 2000, the total number of submissions reviewed was 638. This compared to 618 during the same period of 1999.

The proportion of advertising vehicles that were submitted for review shows a heavy workload oriented towards detail aid activity (46%).

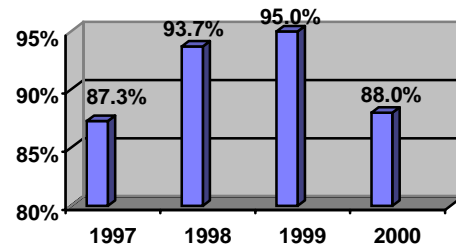
So far in 2000, the total number of submissions reviewed was 1316 compared to the 1998 total of 2354.

During the second quarter of 2000, 82% of the submissions were given a first review response in five days or less and 100% were given a first review response in 10 days or less. This decrease from the previous trend resulted from having three reviewers for most of the quarter, as opposed to the previous staff of 5 Reviewers.

For the year-to-date, 88% were given a first review response in 5 days or less and 100% in 10

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 & 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 advertiser 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: April 1 to June 30, 2000

During the period of April 1 to June 30, 2000, the PAAB Commissioner processed 4 **Stage 2 complaints**. This number brings the total for 2000 to 11. PAAB reviewed 638 advertising pieces during the same period and the year-to-date total is 1316.

Of the 4 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. Of the 2 complaints on advertising that were not PAAB-approved, one was sustained and one was rejected. One complaint was sent to Health Canada for investigation because the advertising 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 11 notice of violation letters in the second quarter.

STAGE TWO DECISIONS

1.

ADVERTISER: Merck Frosst

COMPLAINANT: Glaxo Wellcome

SUBJECT: c00-13 Maxalt (rizatriptan) CPS Insert ad

PRECLEARANCE: Yes

ALLEGATIONS: Alleged onset of action claim in French is not consistent with English wording and product monograph in French is not consistent with the Health Canada approved Product Monograph.

PAAB DECISION: An opinion on the validity of the Product Monograph with respect to the claim in French was sought from Health Canada. Health Canada replied that in their opinion the claim was not valid in English or French because the study data applied only to the wafer formulation. There appeared to be a violation of section 9(1) of the Food & Drugs Act as well as a violation of section PAAB Code section 3.1. Therefore, PAAB withdrew acceptance from all of the APS that contained the claim. Complaint sustained.

PENALTY: Merck Frosst to revise French Product Monograph to address concerns raised by Health Canada. Merck Frosst to immediately cease distribution of all promotional material that contained the questioned claim.

OUTCOME: Merck Frosst agreed. They also took the initiative to inform Byk Canada, who co-promotes Maxalt to cease distribution of the advertising material immediately.

2.

ADVERTISER: Bristol-Myers Squibb

COMPLAINANT: Aventis Pharma

SUBJECT: c00-22 Cefzil (cefprozil) Journal Ad

PRECLEARANCE: Yes

ALLEGATIONS: Alleges graphic of "Otis" the elephant metaphorically displayed as the respiratory tract of a man, combined with the large type headline "Wide Respiratory Coverage" was misleading because the implied claim was not supported by the approved Product Monograph. The ears portrayed as lungs implied lower respiratory tract coverage.

PAAB DECISION: Although subjective in nature, there appeared to be overemphasis on coverage of the complete respiratory tract when the product monograph showed approved claims for upper respiratory tract. PAAB clearance was immediately withdrawn. Showing the approved indication in six point type did not balance the large type headline. Complaint sustained.

PENALTY: BMS to cease distribution of that ad.

OUTCOME: BMS agreed to stop distribution of the ad immediately. The Ad revision was similar in nature to the original ad and showed the title "Wide Upper Respiratory Coverage" over a graphic of the elephant in the man with emphasis on the trunk depicting the upper respiratory tract.

3.

ADVERTISER: Merck Frosst

COMPLAINANT: Searle

SUBJECT: c00-29 – Vioxx (rofecoxib) Hospital Formulary Kit

PRECLEARANCE: No

ALLEGATIONS: Hospital formulary kit was not sent PAAB for preclearance review and, therefore a violation of PAAB Code section 1, *Scope*.

PAAB DECISION: Merck Frosst stated kit was exempt under section 6.6b because it was only distributed on request by hospitals. They provided copies of letters from health professionals to support their position. Searle did not provide any evidence to support their allegation that this was advertising subject to PAAB preclearance review.

OUTCOME: Complaint rejected.

4.

ADVERTISER: Eli Lilly

COMPLAINANT: SmithKline Beecham

SUBJECT: c00-30 Actos (pioglitazone) post-it note distributed to doctors

PRECLEARANCE: No

ALLEGATIONS: Pre-NOC advertising of Actos

PAAB DECISION: With respect to Health Canada policy, item was sent to Health Canada for investigation of possible violation of Food & Drugs Act.

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*

