Pharmaceutical Advertising Advisory Board **October 2000**

PAAB UPDATE

Quarterly Information Bulletin

PAAB
ACTIVITIES DURING THE
THIRD 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.

Get your Code book

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. 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.

General Meeting

The next PAAB General Meeting of Directors will be held Friday, November 10, 2000 at the College of Family Physicians in Mississauga, Ontario from 9 a.m. to 1 p.m.

Misuse of Educational Information

Some pharmaceutical representatives have been using government reports and newsletters in a misleading manner to present unfair attacks on competitors' products. PAAB has received permission from Health Canada to quote the following from a letter to the PAAB Commissioner:

"*The Therapeutic Products Programme (TPP) has been made aware of certain practices by pharmaceutical sponsors regarding the inappropriate dissemination by sales representatives of educational drug information to physicians. The situation involved the distribution of a TPP publication by pharmaceutical sales representatives for advertising purposes in an undesirable manner. The information was presented out of context, in such a way as to discredit a particular drug, thus leading to inappropriate promotions of the competitors' drug products.*

Any scientific information presented by pharmaceutical sales representatives must be given in the right perspective as not to be misleading. When partial information is given, the whole issue is not taken into consideration, and is especially dangerous when it concerns the risks and benefits of drugs.

Focusing only on one aspect and avoiding a balanced representation is a misleading and deceptive practice. This practice reflects poorly on the company and does not display high professional and ethical standards.

To treat, process, sell or advertise any drug in a manner that is false, misleading or deceptive violates provisions in the Food and Drugs Act and Regulations. The TPP grants permission for reproducing material protected by Crown copyright to facilitate the dissemination of important drug safety information. However this permission would not be granted if the intended reproduction would be:

1. *used in an undignified context;*
2. *considered as an unfair or misleading selection;*
3. *used for advertising purposes in an undesirable manner;*
4. *used in a context that may prejudice or harm a third party; or*

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5. *considered inappropriate by the institution in question for legal or other specifiable reasons.*

PAAB's Code of Advertising Acceptance and the Code of Marketing Practices (Rx&D) also have provisions for ethical sales activities of drug products.

TPP encourages pharmaceutical sponsors to refrain from using such inappropriate practices and to consider an ethical code of conduct when designing marketing strategies. This matter is brought to PAAB's attention to increase awareness of such inappropriate practises."

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.

Fair Balance Guidance

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. As a general direction, type size for the indications and limitations statement and the safety information should be proportional to that used for the main body copy, generally **at least** half the size. This information should have good contrast and be placed above the references, footnotes, logo, company name and trademark so that it looks like part of the important message directed at the reader.

Turnaround time Lapse

During the period of the last week of August to the third week of September PAAB fell behind its ten day turnaround to first review standard on 33% of the 262 advertising/promotion systems submitted for preclearance review. The combination of a large volume plus less experienced reviewers than previous years was the main reason for the failure to meet the standard on all submissions. Contributing to the slowdown was the considerable number of new product launches and large detailing pieces. Also, the reviewers spent considerable time encouraging reluctant advertisers to improve their presentations of the indication, limitations and safety information. This helped to reduce their productivity. The Commissioner apologizes for the delay to those advertisers who submitted their submissions in good faith, complete with layout, expecting a turnaround in less than ten working days.

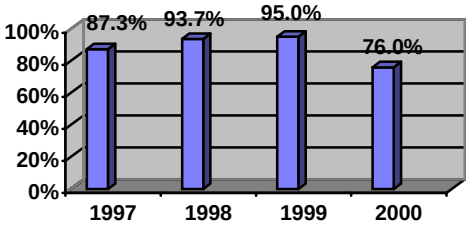
Review Activity

During the period of July 1 to September 30, 2000, the total number of submissions reviewed was 641, with September being the heaviest month at 266. This compared to 686 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 (45%). So far in 2000, the total number of submissions reviewed was 1943 compared to the 1999 total of 2043 for the same period.

During 2000, 76% of the submissions were given a first review response in five days or less and 95% were given a first review response in 10 days or less. During the same period in 1999, 97% were reviewed in 5 days or less and 100% in ten days. This decrease from the previous trend resulted from having three experienced reviewers for the third quarter and from the need to train two new reviewers. PAAB lost seven years of reviewing experience when two people left during the second quarter. Also, the Reviewers spent considerable time encouraging advertisers to comply with the fair balance guidance and to avoid misleading class claims.

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 that 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 to September 30, 2000

During the period of July 1 to September 30, 2000, the PAAB Commissioner processed six (6) **Stage 2 complaints**. This number brings the total for 2000 to 17. PAAB reviewed 641 advertising pieces during the same period and the year-to-date review total is 1943.

Of the 6 complaints, 5 were generated from advertising that had been previously PAAB-reviewed. One complaint was rejected. The other 4 resulted in withdrawal of PAAB's previous acceptance. Of those four, the reversal of the PAAB acceptance was based on new information since the time of approval of the APS. One complaint was sent to Health Canada for investigation because it was not clear to PAAB that the alleged misleading advertising was created and distributed by a pharmaceutical company.

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 4 notice of violation letters in the third quarter.

STAGE TWO DECISIONS

1.

ADVERTISER: Wyeth-Ayerst

COMPLAINANT: ICN (referred by Health Canada)

SUBJECT: c00-40 Shoppers Drug Mart Newsletter

PRECLEARANCE: No

ALLEGATIONS: Violations of several provisions of section 5 because of unfair and unsubstantiated comparative claims regarding therapeutic equivalence.

PAAB DECISION: Refer back to Health Canada for investigation of potential violations of Food & Drugs Act. Claims in that newsletter would be rejected by PAAB but the Wyeth-Ayerst sponsorship or involvement with the pharmacy was not clearly stated. Therefore, it was not clear that the material fell within the PAAB mandate.

2.

ADVERTISER: Schering

COMPLAINANT: Glaxo Wellcome

SUBJECT: c00-32 Nasonex Detail Material

PRECLEARANCE: yes

ALLEGATIONS: The value for the intranasal bioavailability of Flonase (fluticasone) of 1.8% shown in the data presentation is misleading because new information contradicts that value (5.5, 5.10).

PAAB DECISION: Sustained. The Flonase product monograph does not state a value for intranasal bioavailability. The claim was accepted by PAAB based on the 1995 evidence presented by Schering. Glaxo presented two scientific papers that have emerged in recent years that appear to contradict the original data (s3.2). Also, the comparative bioavailability has no proven clinical relevance (s5.4). Therefore, the claim is no longer acceptable. Also, the PAAB acceptance period had expired.

PENALTY: Schering to immediately cease distribution of any advertising that contains the comparative claim to Flonase intranasal bioavailability. Schering acted in good faith by distributing the original claim based on PAAB approval.

OUTCOME: Schering complied with the decision.

3.

ADVERTISER: Lundbeck

COMPLAINANT: Smithline Beecham

SUBJECT: c00-41 Celexa Detail material

PRECLEARANCE: Yes

ALLEGATIONS: The claim "Celexa has been shown not to interact with drugs such as :… TCAs, beta-blockers, digoxin, …" is not within the limitations of the Product monograph (s3.1)

PAAB DECISION: Partially Sustained. The claim was first approved at the time of launch of Celexa. I agreed with the Lundbeck argument that the headline "low potential for drug interactions" did not state that no interactions occurred. PAAB does not keep old versions of product monographs and therefore, a monograph change may occurred with respect to the listed interactions. Although interactions with metoprolol and digoxin are listed in the product monograph they are not considered to be significant enough to affect therapy. However, there is a significant interaction with respect to the TCAs imipramine and desipramine (s3.1) and a note of caution is called for (s2.4). The Lundbeck argument that a footnote disclaimer directs the reader to the product monograph for more information is ruled as insufficient to avoid being misleading.

PENALTY: Immediate withdrawal of PAAB acceptance and Lundbeck to cease distributing the APS with the subject interaction claims.

OUTCOME: Lundbeck agreed with the decision.

4.
ADVERTISER: Servier

COMPLAINANT: Merck Frosst

SUBJECT: c00-42 Coversyl Detail Material

PRECLEARANCE: Yes

ALLEGATIONS: Chart showing comparative costs of drug therapy did not include once daily dosing and cost for Vasotec. Once daily as an approved dosing schedule in the product monograph. Servier had agreed to make the change in their next cycle of advertising but Merck frosst asked for immediate withdrawal of the material.

PAAB DECISION: Sustained. To be complete and fair, the once daily cost for Vasotec should be shown with the twice daily cost. The chart had appeared in advertising for almost three years. Therefore I considered that adding a sticker stating Vasotec once daily with a cost would be sufficient to reduce the cost and disruption to Servier.

PENALTY: Withdrawal of PAAB acceptance pending administration of a sticker with the Vasotec once daily cost information on APS that had current PAAB approval. Material would be created in January.
OUTCOME: Servier agreed to the decision. However, the Commissioner rejected their action plan which allowed 35 days for creation of the one line sticker. The Commissioner notes that companies have printed multi-page detail aids the day after PAAB acceptance. The Commissioner suggested two weeks.

5.
ADVERTISER: Bristol-Myers Squibb

COMPLAINANT: Merck Frosst

SUBJECT: c00-43 Avalide Detail Material

PRECLEARANCE: yes

ALLEGATIONS: The claim "Demonstrated greater efficacy than Cozaar + HCTZ" is misleading because it is based on a study that does not compare like doses (s5.2).

PAAB DECISION: Sustained. The claim contravenes section 5.2 which states comparisons should be drawn between drugs under the same conditions of use (e.g maximum vs maximum doses). This did not occur in the Oparil study.

PENALTY: Withdrawal of PAAB clearance and cessation of distribution of the APS containing the claim.
OUTCOME: Bristol-Myers Squibb/Sanofi-Synthelabo agreed to cease distribution.

6.
ADVERTISER: Merck Frosst

COMPLAINANT: Bristol-Myers Squibb / Sanofi-Synthelabo

SUBJECT: c00-38 Cozaar/Hyzaar Detail aids containing claims based on a meta-analysis

PRECLEARANCE: Yes

ALLEGATIONS:. Violations of s5.2 and s5.7 because of use of meta-analysis to support a comparative claim. Also allege Conlin meta-analysis methodology is biased and is not appropriate to compare agents in a widely varying patient population.

PAAB DECISION: Rejected. s5.10 allows use of peer-reviewed published meta-analysis to support comparative claims. The author explains why the weighting was appropriate to correct for the size of the different studies and also why it is an appropriate method for hypertensive studies.

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*