Pharmaceutical Advertising Advisory Board **January 2001**

PAAB UPDATE

Quarterly Information Bulletin

PAAB
ACTIVITIES DURING THE
FOURTH QUARTER OF 2000

Year 2001 marks the 25th 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.

Annual/General Meeting Highlights

The PAAB Annual/General Meeting of Directors was held Friday, November 10, 2000 at the College of Family Physicians in Mississauga, Ontario. The next Annual/General Meeting will be held on April 20, 2001 from 9 a.m. to 1 p.m. at the same location.

- The PAAB members voted in a new member, Canada's Association for the Fifty-Plus (CARP). This step reflects the Board's goal to increase consumer/patient membership in the PAAB. Mr. James Dunsmuir attended as the delegate from CARP.
- Dre Francine Mathieu-Millaire represented La Fédération des médecines spécialistes du Québec as an invited observer.
- Sheila Purcell represented the Health Charities Council of Canada (HCCC)as an invited observer.
- The fee schedule and budget for 2001 was approved.
- The directors agreed to seek consultation from doctors, pharmacists and the pharmaceutical industry on the subject of using abstracts and poster presentations as references for advertising claims.

Slowing of the Review Process

PAAB Code section 2.4 requires that advertising exhibit a note of caution with respect to presenting a balance of risk to benefit information. Section 2.1 requires that the Health Canada approved indication and limitations stated in the product monograph be presented in a clear manner. Last May Commissioner Chepesiuk issued an advisory letter to the industry indicating that Health Canada had advised PAAB that the inclusion of the indication and safety information in small type footnotes was seen to be misleading and in violation of the Food & Drugs Act. There was a Health Canada request that the PAAB change its application of sections 2.4 and 2.1 to show that the indications and safety information were seen clearly as important information in advertising. Commissioner Chepesiuk reports that this change

LOOK INSIDE

in application of the Code has slowed the review process considerably due to the reluctance of some advertisers to present this information in a clear manner. There is still a tendency of pharmaceutical advertisers to either not include any safety information or to present it in small type footnotes in an obscure part of the advertising, usually below the logo and trademark information. This information appears to be important to everyone except the advertisers themselves and the reviewers spend a lot of time explaining the need for revision during the PAAB review process. Commissioner Chepesiuk asks for the cooperation of all advertisers with the PAAB Reviewers during the review process. The Reviewers work hard to convince advertisers of the need to do it. Agencies should inform their creative people of the need to include the indication, limitations and safety information in a type size similar to the main message copy, in a prominent location with good contrast. Addressing the issue early in the creative process and not at the PAAB review stage would save everybody's time.

New Senior Reviewer

Commissioner Ray Chepesiuk is pleased to announce that Assistant Commissioner John Wong has been appointed Senior Reviewer, effective January 1, 2001. John has been a Reviewer at PAAB for more than 3 years. John will be responsible for supervising the review process and for Reviewer training.

Get DTCRx Advice

We remind you that PAAB will give an advisory opinion on specific projects that involve advertising or information directed at the general public. Currently, companies cannot advertise prescription drugs except for name, price, and quantity 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. Advertisers should note that the PAAB members have agreed to the Health Canada request that it be copied on submissions reviewed by the PAAB.

Misleading Class Claims

With respect to product advertising, this is a reminder that 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

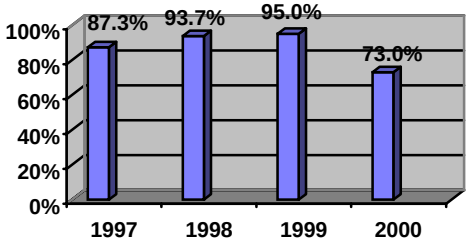
During the period of October 1 to December 31, 2000, the total number of submissions reviewed was 658. This compared to 780 during the same period of 1999.

The proportion of advertising vehicles that were submitted for review shows a heavy workload oriented towards detail aid activity (52%).

In 2000, the total number of submissions reviewed was 2662 compared to the 1999 total of 2822. This was the third highest submission review volume in the 24 year history of the PAAB.

During the fourth quarter of 2000, 47% of the submissions were given a first review response in five days or less and 99% were given a first review response in 10 days or less. For all of 2000, the turnaround to first review in five days or less was 73%. This decrease from the rate set in 1999 resulted from having fewer experienced reviewers, a workload more weighted towards detail material and some particularly combative advertisers. Year 2000 saw product launches in particularly competitive therapeutic areas. Arguing with the PAAB Reviewers about unacceptable claims and support material that most stakeholders view as unethical serves to slow down the review process.

Share of ads with first review in 1- 5 days



Fee Schedule Revised

You can get a copy of the 2001 PAAB fee schedule from the PAAB Web-site www.paab.ca

or on request from the PAAB office. There is no increase of the regular fees, and there are new fees for consultation meetings as well as written advisories on Direct-to-Consumer messages.

"Pharmacy Bulletin Board"

We remind advertisers that the faxed publication "Pharmacy Bulletin Board" is not exempt from the PAAB Code of Advertising Acceptance. Commercial messages (price change, formulary listing, new package size, out of stock messages) are exempt from PAAB review in any publication. Note any inclusion of product claims (therapeutic, economic, QOL, merit) would require PAAB review and inclusion of prescribing information with the fax distribution.

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. Allegations involving public safety are sent without delay to Health Canada for investigation.

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 to December 31, 2000

During the period of October 1 to December 31, 2000, the PAAB Commissioner processed 7 **Stage 2 complaints**. This number brings the total for 2000 to 26. PAAB reviewed 658 advertising pieces during the same period.

Of the 7 complaints, 4 were generated from advertising that had been previously PAAB-reviewed (there were two complaints about he same APS). Two of these complaints were rejected and two sent by physicians were referred to Health Canada for investigation because of safety allegations. Of the 3 complaints on advertising that were not PAAB-approved, all three were sustained. For the first time since the revision of the PAAB complaint process in 1996, the Commissioner had to refer two cases involving the same manufacturer, Taro Pharma, to Health Canada because of failure to comply with the PAAB ruling. There was also an alleged violation of the Food & Drugs Act section 9(1) in the Taro advertising.

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 10 notice of violation letters in the second quarter bringing the total for the year to 26.

STAGE TWO DECISIONS

1.

ADVERTISER: Axcan

COMPLAINANT: Ferring

SUBJECT: c00-48 Salofalk (5-ASA) journal ad

PRECLEARANCE: Yes

ALLEGATIONS: Section 3.1 – an indication not approved by Health Canada is being promoted because "IBD" is used.

PAAB DECISION: IBD stands for inflammatory bowel disease. The product monograph shows an indication for ulcerative colitis and Crohn's disease which are inflammatory bowel diseases. Therefore, the ad is not misleading. The indication should be stated in full in future ads to clarify the intent. Rejected.

2.
ADVERTISER: Glaxo Wellcome

COMPLAINANT: Merck Frosst

SUBJECT: c00-51 Imitrex (sumatriptan) Sample kit

PRECLEARANCE: No

ALLEGATIONS: Section 1 - sample kit is advertising that should have been precleared by PAAB.

PAAB DECISION: Item is advertising. Sustained.

PENALTY: Glaxo Wellcome should submit the sample kit for PAAB preclearance review.

OUTCOME: Rx&D notified of Rx&D Code of Marketing Practices infraction. Glaxo Wellcome agreed with ruling and sent notice to their field force to cease distribution pending review by the PAAB.

3.
ADVERTISER: SmithKline Beecham

COMPLAINANT: Eli Lilly

SUBJECT: c00-53 Avandia advertising

PRECLEARANCE: Yes

ALLEGATIONS: Section 3.1 - Once daily dosing claims are misleading because product monograph states twice a day is an option and most studies use twice a day dosing.

PAAB DECISION: Product Monograph dosing section shows both once-a-day and twice-a-day options with no limitations. Rejected.

4.
ADVERTISER: Taro Pharma

COMPLAINANT: DuPont Pharma

SUBJECT: c00-55 Detail Aid

PRECLEARANCE: No.

ALLEGATIONS: Section 1 - not submitted for preclearance review. False interchangeability claim (2.1), lack of safety information (2.4), prescribing information was over edited and removed important safety information (7.6).

PAAB DECISION: Item was not submitted for PAAB review. Prescribing information does not meet PAAB Code requirements because important safety information was missing. Sustained. Sent to Health Canada for investigation into safety allegation.

PENALTY: Cease distribution and submit APS to PAAB for review.

OUTCOME: Taro chose not to comply with the PAAB ruling and they stated that they were consulting their lawyers about PAAB preclearance review. The PAAB Commissioner sent the case to Health Canada because of an alleged violation of the Food & Drugs Act in addition to noncompliance with the PAAB ruling. We are awaiting the results of the investigation by Health Canada.

5.
ADVERTISER: Taro Pharma

COMPLAINANT: DuPont Pharma

SUBJECT: c00-57 Mailer

PRECLEARANCE: No.

ALLEGATIONS: Not submitted to PAAB for preclearance review (2.1) and prescribing information does not conform to PAAB code requirements.

PAAB DECISION: Sustained. Extensive important safety information was missing from the prescribing information.

PENALTY: Cease distribution and submit APS to PAAB for review.

OUTCOME: Taro chose not to comply with the PAAB ruling. PAAB Commissioner sent the case to Health Canada because of an alleged violation of the Food & Drugs Act in addition to noncompliance with the PAAB ruling. We are awaiting Health Canada's ruling.

6.

ADVERTISER: Boehringer Ingelheim

COMPLAINANT: Physician

SUBJECT: c00-72 Mobicox (meloxicam) advertising

PRECLEARANCE: Yes

ALLEGATIONS: Comparative price claims to Vioxx (rofecoxib) and Celebrex (celexicob) implied that the three agents were therapeutically equivalent. The physician believed that patient safety was compromised if Mobicox was prescribed instead of the other two drugs. The physician believed Mobicox was not COX-2 selective.

PAAB DECISION: Referred to Health Canada because of the patient safety allegation. Health Canada stated that it was not clear whether or not there was a safety issue. All three agents are COX-2 selective but may vary in their degree of selectivity. They believed that the price comparison implied therapeutic equivalency when no comparative studies between the agents had been done. Health Canada advised PAAB that this advertising was misleading and violated the Food & Drugs Act section 9(1).

PENALTY: PAAB Commissioner advised Boehringer Ingelheim that PAAB approval was immediately withdrawn and that the Mobicox advertising campaign should be revised to remove the Health Canada allegation of the misleading comparison to Vioxx and Celebrex.

OUTCOME: Pending. Notice was sent to Boehringer Ingelheim December 22, 2000 and no formal reply was received before this printing date.

7.

ADVERTISER: Boehringer Ingelheim

COMPLAINANT: Physician

SUBJECT: c00-73 Mobicox (meloxicam) advertising

PRECLEARANCE: Yes

ALLEGATIONS: Comparative price claims to Vioxx (rofecoxib) and Celebrex (celexicob) implied that the three agents were therapeutically equivalent. The physician believed that the agents were sufficiently different in chemical structure that therapeutic results would vary. The physician believed Mobicox was not COX-2 selective.

PAAB DECISION: Referred to Health Canada because of the patient safety allegation. Health Canada stated that it was not clear whether or not there was a safety issue. All three agents are COX-2 selective but may vary in their degree of selectivity. They believed that the price comparison implied therapeutic equivalency when no comparative studies between the agents have been done. Health Canada advised PAAB that this advertising was misleading and violated the Food & Drugs Act section 9(1).

PENALTY: PAAB Commissioner advised Boehringer Ingelheim that PAAB approval was immediately withdrawn and that the Mobicox advertising campaign should be revised to remove the Health Canada allegation of the misleading comparison to Vioxx and Celebrex.

OUTCOME: Pending. Notice was sent to Boehringer Ingelheim December 22, 2000 and no formal reply was received before this printing date.

Review Volume History

Human Drug Advertising/Promotional Systems

1996	1997	1998	1999	2000
2441	2540	2354	2742	2591

Complaints History

Stage Two Decisions

1996	1997	1998	1999	2000
28	14	26	24	26

Monitoring History

Violation Notices Initiated by PAAB

1996	1997	1998	1999	2000
14	67	16	21	26

PAAB STAFF

Commissioner: Ray Chepesiuk
Senior Reviewer: John Wong
Reviewers/Assistant Commissioners:
Colin Campbell
Yin-Ling Man
Lucia Kim
Pauline Dong
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

Canadian Medical Association (CMA)
Canadian Pharmacists Association (CPhA)
Canada's Research-Based Pharmaceutical Companies (Rx&D)
Canadian Drug Manufacturers Association
Canada's Association for the Fifty Plus (CARP)
Canadian Association of Medical Publishers (CAMP)
Consumers' Association of Canada (CAC)
Nonprescription Drug Manufacturers Association of Canada (NDMAC)
Association of Medical Advertising Agencies (AMAA)
Advertising Standards Canada (ASC)

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

Health Canada is an ex-officio observer

PAAB Executive Committee

Chair Dr. Reg Perkin
Vice-Chair Gloria Bowes
Treasurer Lorenzo Biondi
Member John Suk
Member Ken Stallman
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 and give advice on direct-to-consumer prescription drug advertising.*
- *Training, adjudicating complaints, administering penalties, reporting of infractions, and other activities to encourage compliance.*

For information or if you have comments:

Pharmaceutical Advertising Advisory Board
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e-mail: info@paab.ca

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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