Pharmaceutical Advertising Advisory Board **April 2001**

PAAB UPDATE

Quarterly Information Bulletin

PAAB
ACTIVITIES DURING THE
FIRST QUARTER OF 2001

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

The PAAB Annual/General Meeting of Directors will be held held Friday, April 20, 2001 at the College of Family Physicians in Mississauga, Ontario.

- At the last General Meeting, 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. Commissioner Chepesiuk will present a recommendation for a Code revision, that is based on the responses, to the Board.

Health Canada Advisories

Health Canada has issued two recent advisories about drug advertising. In December 2000, PAAB received "Advertising Campaigns of Branded and Unbranded Messages" with respect to Direct-to-Consumer (DTC) communications. In March, PAAB received "Guidance on the Interpretation of the TPP policy – The Distinction Between Advertising and Other Activities" with respect to institutional DTC messages.

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.

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PAAB Workshops

We get requests for information about PAAB workshops. The PAAB Commissioner has appeared at the OPMA Education Day last year and will appear in the April 2001 Education Day conducted by the PMCQ. The PAAB will conduct onsite meetings or mini-workshops for individual pharmaceutical companies or advertising agencies on request, for a fee of $350 plus travel expenses. Contact the Commissioner for more information.

New Senior Reviewer

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. When necessary, clients should contact John for clarification of PAAB review policy, when an impasse on individual reviews is reached, and to set up meetings for product launch information or when otherwise it is necessary.

Misleading Class Claims (reprise)

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.

Branding

Marketers are aware of the importance of branding, a term that has many definitions. I recently saw a definition of branding by Doug Jamieson, the President of Charity Village – "*A brand is an image supported by truth*". I believe that would be a good guiding thought for pharmaceutical marketers when they create drug advertising. Drug advertising should reflect the truth known about a drug product. Long term success is a function of trust and the resultant credibility.

Relative Risk Explained

For an explanation of the importance of showing the absolute risk as opposed to relative risk data, see the *Therapeutics Initiative* Web-site article "Evidence Based Drug Therapy, What Do the Numbers Mean?" at www.interchg.ubc.ca/jauca/.

Review Activity

During the period of January 1 to March 31, 2001, the total number of submissions reviewed was 670. This compared to 706 during the same period of 2000.

Detail Aids comprised 40% of the overall activity.

During the first quarter of 2001, 57% of the submissions were given a first review response in five days or less and 96% were given a first review response in 10 days or less. To help improve the turnaround time, the PAAB Commissioner asks sponsors and their agencies to respect the PAAB Code when advertising is being created.

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: January 1 to March 31, 2001

During the period of January 1 to March 31, 2001, the PAAB Commissioner processed 9 **Stage 2 complaints**.. PAAB reviewed 670 advertising pieces during the same period.

Of the 9 complaints, 6 were generated from advertising that had been previously PAAB-reviewed Portions of these complaints were upheld in all cases and most of them did not involve overtly misleading presentations. Based on the number and the nature of the complaints, it appears that the pharmaceutical industry is asking the PAAB for a tighter interpretation of the PAAB Code. Of the 3 complaints on advertising that were not PAAB-approved, all three were sustained. One required a retraction letter to be sent to the original recipients.

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 12 notice of violation letters in the first quarter of 2001.

STAGE TWO DECISIONS

1.
ADVERTISER: Sanofi/Synthelabo & Bristol–Myers Squibb

COMPLAINANT: Boehringer Ingelheim

SUBJECT: C00-49 journal ad

PRECLEARANCE: yes (March 2000)

ALLEGATIONS: Primary issue was a data presentation showing a risk reduction of 25% based on combining the risk reduction shown with ASA and with Plavix in separate studies. A secondary issue was that the statement of risk reduction was not accurate in that it did not state "combined risk" in the body copy to reflect the meaning of the data. Having it in small type in a footnote was not sufficient.

PAAB DECISION: Rejected primary issue because the data presentation had been the subject of a previous complaint and had been reviewed with no objection by Health Canada. Sustained the complaint on the secondary issue because the word "combined" had been raised during the review of the ad and it was moved to a small type footnote by the advertising agency prior to going to final print.

PENALTY: Withdrawal of PAAB acceptance and cease distribution of the ad.

OUTCOME: Agreed. Closed.

2.
ADVERTISER: AstraZeneca (AZ)

COMPLAINANT: GlaxoSmithKline (gsk)
SUBJECT: c00-60 Detail Aid

PRECLEARANCE: Yes (March 2000)

ALLEGATIONS: Seven allegations, related to section 4.2 data presentations, raised by gsk involving use of the "Zomco" study, comparative claims and data presentations.

PAAB DECISION: Agreed with gsk on three of the allegations related to lack of a statistically significant difference not been clearly stated. The other points were rejected because AZ appeared to represent the study results in an acceptable manner.

PENALTY: Withdraw PAAB acceptance and AZ to inform representatives to return all copies of the detail aid to the head office for destruction.

OUTCOME: Agreed. Closed.

3.
ADVERTISER: Serono

COMPLAINANT: Berlex

SUBJECT: Rebif (interferon beta-1a) Information

pamphlet distributed through nurses or physicians at clinics.
PRECLEARANCE: No.

ALLEGATIONS: This is advertising not patient information and the comparative claims are unsubstantiated and unfair because they are based on an abstract presentation of preliminary results of a U.S. mail-in survey from patients and Serono Rebif was not available in the U.S. to those respondents. There was a mix of product monograph data and data derived from the survey.

PAAB DECISION: This is not patient information. It is advertising with a potential to mislead bcause the comparison was not based on the results of peer-reviewed, published, head-to-head studies.

PENALTY: Regarded as a serious violation of the Code and PAAB requested a retraction letter sent to the original recipients stating that this was advertising that was not reviewed by the PAAB. Serono should inform their sales representatives to retrieve and dispose of outstanding information kits.

OUTCOME: Agreed. Closed.

4.
ADVERTISER: Bayer

COMPLAINANT: Abbott

SUBJECT: Avelox journal ad/CPS Insert

PRECLEARANCE: Yes (October 2001)

ALLEGATIONS: Three allegations related to mixing pharmacokinetic and clinical data, a comparative claim 'greater and faster bacterial eradication', and a claim of "works fast"

PAAB DECISION: Reject two claims because they are accurate, complete and clear. Sustain complaint versus the comparison claim of "greater and faster eradication rates" because it is not fully substantiated.

PENALTY: Withdraw PAAB acceptance and replace CPS Inserts.

OUTCOME: Agreed. Closed.

5.
ADVERTISER: Novo Nordisk

COMPLAINANT: Eli Lilly

SUBJECT: Novolin (insulin, Human Biosynthetic) Information kit to be distributed by health professionals to patients.

PRECLEARANCE: No.

ALLEGATIONS: This is not "patient information" because there is emphasis on switching patients to Novolin from Eli Lilly discontinued Humulin products. It should have been precleared by PAAB. Lilly alleges that this kit is causing confusion in the marketplace and misrepresents Eli Lilly's marketing efforts.

PAAB DECISION: Item is "advertising" not "patient information" because it is promoting the sale of Novolin through encouragement of switching to Novolin products. It should have been precleared by the PAAB. Confusion claim is rejected because Eli Lilly has provided no evidence of that, the listed items in the Novolin information are identical to a list provided by Eli Lilly to the PAAB, and information from both companies might indicate that both companies' field representatives were the source of the confusion.

PENALTY: Novo Nordisk should discontinue distribution and send the information for PAAB review.

OUTCOME: Novo Nordisk had already exhausted supply of the kit and they are receiving requests for components of the kit. They agreed to send those components to the PAAB for review. Closed.

6.
ADVERTISER: Boehringer Ingelheim (BICL)

COMPLAINANT: Merck Frosst

SUBJECT: three items: business card holder, company generated newsletter,, journal ad in 'Benefits Canada'.

PRECLEARANCE: No

ALLEGATIONS: All items should have been precleared. The business card holder contains a comparison claim that is not consistent with a Health Canada opinion of previous Mobicox advertising. The newsletter was not completely independently produced.

PAAB DECISION: All items should have been precleared. The business card holder contains a comparison claim that would not be accepted by the PAAB based on a Health Canada opinion of previous Mobicox advertising. The newsletter was not completely independently produced. Health Canada had previously provided an opinion that the target audience for journals such as "Benefits Canada' was not considered to be 'general public' because of the readers specialized knowledge of health care. Thus the target audience would be considered to fall under the scope of the PAAB preclearance requirement.

PENALTY: Discontinue distribution immediately. Retrieve violative material. Rx&D and Health Canada informed of violation

OUTCOME: BICL indicates they will stop distribution but does not mention retrieval in their response. Not closed as of March 31, 2001.

7.

ADVERTISER: Aventis & Procter&Gamble

COMPLAINANT: Private Physician

SUBJECT: Actonel (risedronate) journal ad
PRECLEARANCE: Yes (September 2000)

ALLEGATIONS: Data presentation shows relative risk reduction (RRR) data alone in contravention of Code section 4.2.

PAAB DECISION: Agree with complainant that additional information should accompany the RRR presentation. Upon investigation, it appears that this was the only Actonel APS out of ten reviewed at the same time that this RRR presentation appeared in this manner. All the other Actonel APS shows the absolute risk reduction in the same chart. Agency has agreed to the PAAB Reviewer request for change but the change did not make it into the final version. This appears to be an unintentional oversight on both the PAAB reviewer and the advertiser.

PENALTY: Withdraw PAAB clearance and cease distribution of the ad by May 2001.

OUTCOME: Agreed. Closed.

8.

ADVERTISER: Boehringer Ingelheim

COMPLAINANT: Private Physician

SUBJECT: Aggrenox (ASA/Extended Release dipyridamole) Journal Ad

PRECLEARANCE: Yes (November 2000 based on previous May 2000 acceptance)

ALLEGATIONS: First allegation was noting the absence of the discontinuation rate in a data presentation that does not provide sufficient information to compare. The second allegation was noting a presentation of stroke data was insufficient to provide risk/benefit information.

PAAB DECISION: Agreed on first allegation that the presentation, although not overtly misleading, would be improved by the addition of the discontinuation rates. PAAB did not agree with the second allegation because the presentation of the stroke data was consistent with the presentation of that data in the Health Canada approved product monograph.

PENALTY: Withdraw PAAB approval and cease distribution of the ad.

OUTCOME: Agreed. Closed.

9.

ADVERTISER: Warner-Lambert Consumer Health Care

COMPLAINANT: Carter-Horner

SUBJECT: Bonamine (meclizine) Detail Aid

PRECLEARANCE: Yes (October 2000)

ALLEGATIONS: Comparative claim based on 1956 study does not meet the standard set in the PAAB Code as section 5.2 based on flawed protocol and insufficient statistical analysis.

PAAB DECISION: Unusual case because advertiser based the advertising on product monograph data that includes the 1956 study. Therefore, the PAAB reviewer accepted the data presentation. However, upon close scrutiny, the study does appear to be flawed and use of the results is potentially misleading.

PENALTY: Withdraw PAAB clearance and cease distribution of the ad.

OUTCOME: Agreed. Closed. PAAB wrote a letter to Health Canada to advise them to review the Bonamine

Product monograph because inclusion of comparative claims based on the questioned 1956 study did not appear to meet the Health Canada Principles regarding comparison of therapeutic aspects.

PAAB STAFF

Commissioner: Ray Chepesiuk
Senior Reviewer: John Wong
Reviewers/Assistant Commissioners:
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Yin-Ling Man
Lucia Kim
Pauline Dong
Submission Co-ordinator:
Carol Johnston
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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:

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

PAAB

CCPP