Pharmaceutical Advertising Advisory Board **July 2002**

PAAB UPDATE

PAAB
ACTIVITIES DURING THE
SECOND QUARTER OF 2002

Year 2002 marks the 26th year for the 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 Reviewer Hired

Commissioner Ray Chepesiuk is pleased to announce that PAAB has hired a new bilingual Reviewer, Mr. Patrick Massad, effective August 6, 2002. Patrick is a graduate of the University of Toronto and has been a practicing hospital pharmacist in Toronto. He becomes the sixth reviewer in the current PAAB staff. Patrick will be trained under the supervision of Senior Reviewer John Wong.

Strategic Planning

On behalf of the Board, the PAAB Executive Committee has chosen The Everson Company Inc. to facilitate strategic planning. It is anticipated prep work will be completed prior to a November 15, 2002 meeting of the Board to finalize the plan.

Patient Information

From a regulatory perspective, there appears to be some confusion among PAAB clients about patient information due to their misuse of terminology. You should refer to the Health Canada guideline "The Distinction Between Advertising and Other Activities" for a description of various activities.

Patient Information is information given to a person who has been prescribed a drug and the information about the particular drug is designed to help the patient achieve optimal therapeutic results. Therefore, *Patient Information* cannot be distributed to the general public. You can distribute information to the general public by means of a *Consumer Brochure,* also described in the Health Canada guideline. There should be no emphasis on a particular drug in this vehicle, otherwise it may violate Federal advertising law. According to the Health Canada guideline, *Patient Information* may be considered "labeling" if it accompanies the prescription. If Health Canada has reviewed and approved Patient Information as labeling, there is no requirement for PAAB review. Also, *Patient Information* that does not accompany the prescription may be considered advertising.

Patient Information distributed through a health professional requires PAAB review under Code s6.4, amended April 2002. This includes health professional referral to a pharma company controlled web-site source of information. (continued on page 2)

LOOK INSIDE

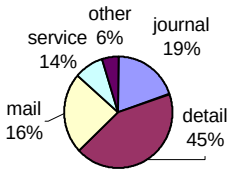
The exemption from PAAB review covers Patient Information that goes directly from company to patient without a health care professional intermediary, e.g. a subscription program or a web-site that does not involve health care professional referral.

Review Activity

During the period of April 1 to June 30, 2002, the total number of submissions reviewed was 786. This compared to 650 during the same period of 2001, a 20% increase.

In 2002, the total number of submissions reviewed year-to-date was 1576, an 18% increase compared to the 2001 total of 1327.

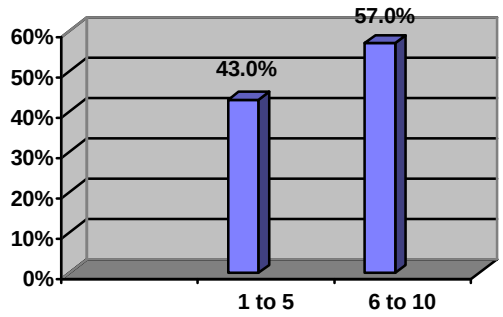
The proportion of advertising vehicles that were submitted for review shows 45% of the workload oriented towards detail aid activity.



Share of ads reviewed

During the first half of 2002, 43% of the submissions were given a first review response in five days or less and 100% were given a review response in 10 days or less.

Turnaround Time to First review



Faxed Advertising

This is a reminder that company-sponsored faxed advertising messages require PAAB preclearance review under Code s6.2 and all Code s7 Prescribing Information requirements apply.

Also, I have received comments that, in some cases, the physical quality of faxed information has been substandard to the point of being illegible. This may be due to the quality of the receiving equipment. However, if you are communicating important information, you should be aware of the ability to read your information.

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 about pharmaceutical advertising. Sponsors 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 advertiser responds in writing to the complainant. The complainant then has three options: continue discussion with the advertiser; accept the advertiser's response; or 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, 2002 to June 30, 2002

During the period of April 1 to June 30, the PAAB Commissioner processed 5 **Stage 2 complaints**. This number brings the total for 2002 to 11. PAAB reviewed 1576 advertising pieces during the first six months.

Of the 5 complaints, 2 were generated from advertising that had been previously PAAB-reviewed. 1 of these complaints resulted in withdrawal of PAAB's previous acceptance. The other was sent to PAAB by a physician. 1 complaint on advertising that was not

PAAB-approved was sustained, one was rejected and 1 was referred to Health Canada. Of the 2 complaints that were sent to PAAB by physicians, 1 was sent to Health Canada for action because it related to a product that had not received Notice of Compliance in Canada.

PAAB has continued to regularly **monitor** journals, the Internet, selected conferences and receive direct-mail/detail aid materials collected by health professionals as part of its monitoring program. During the second quarter of 2002, a total of 9 monitoring letters were. This brings the total for this year to 16. Three cases were referred to Health Canada because of perceived Direct-to-Consumer Advertising violations.

Update on complaint c02-11 reported in the April 2002 PAAB UPDATE: Pharmacia rescinded the stage 3 appeal request. Pharmacia provided documentation that the publisher controlled the layout causing the linkage of non-branded material to product advertising. The PAAB Commissioner ruled it was still a violation of the PAAB Code and agreed to rescind the notice of violation to Rx&D because it appeared to be unintentional on Pharmacia's part.

STAGE TWO DECISIONS

1.

ADVERTISER: Novartis

COMPLAINANT: Bristol-Myers Squibb

SUBJECT: c02-15 Diovan (valsartan) detail aid

PRECLEARANCE: yes

ALLEGATIONS: BMS alleges use of Conlin et al meta-analysis is not sufficient evidence to support a comparative claim between irbesartan and valsartan because the only two studies selected in the meta-analysis were abstracts. If they were used apart from the meta-analysis, the PAAB would not accept the claim according to Code sections 5.7 and 3.1 that require well-controlled, adequate studies.

PAAB DECISION: Sustained. While section 5.10 allows for use of published meta-analyses to support comparative efficacy claims, this appears to be an exceptional case. The author states that not all of the studies included were "optimal". Therefore, a comparative claim based on the support of only less than optimal studies i.e. abstracts, does not meet the spirit and letter of the PAAB Code.

PENALTY: Cease distribution and recall all material containing this comparative claim from the representatives.

OUTCOME: pending Novartis response at publication time

2.

ADVERTISER: Novartis

COMPLAINANT: Physician

SUBJECT: c02-18 Exelon (rivastigmine) journal ad approved by the PAAB in June 2000.

PRECLEARANCE: yes

ALLEGATIONS: Alleges a violation of s3.1 because advertisement does not state clinical significance for relief of Alzheimer's Disease symptoms.

PAAB DECISION: Rejected. All of the claims in the ad are consistent with data in the Product Monograph. A basic requirement for approval of data by Health Canada is clinical significance. Therefore, the ad is not misleading and there is no PAAB Code violation.

OUTCOME: No Further action required.

3.

ADVERTISER: Biogen

COMPLAINANT: Serono

SUBJECT: c02-26 Avonex letter signed by the Medical Director regarding the EVIDENCE study

PRECLEARANCE: no

ALLEGATIONS: Letter is promotional and would require PAAB review.

PAAB DECISION: Biogen argues that the letter was a medical communication, not promotional and there was much interest in the EVIDENCE study by physicians, justifying its widespread distribution. The distribution of this promotional item was mostly unsolicited, therefore PAAB preclearance was required under s6.2.

PENALTY: Cease distribution and submit future material for PAAB review. Health Canada was copied on the correspondence.

OUTCOME: Biogen agrees to comply with the decision.

4.

ADVERTISER: Eli Lilly

COMPLAINANT: Janssen-Ortho

SUBJECT: c02-27 Zyprexa (olanzapine) dosing card

PRECLEARANCE: no

ALLEGATIONS: Three allegations (1) promotion of unapproved claim for bipolar depression (2) the approved

indication is obscure (3) the card was not approved by the PAAB.

PAAB DECISION: Rejected 3 allegations. Information on the card is consistent with the Product Monograph. The indication is stated in a manner consistent with other APS approved at the same time. Eli Lilly corrected their oversight and submitted the card for PAAB review and subsequent approval. Janssen-Ortho made additional allegations that would be more appropriately handled by Rx&D and Health Canada

OUTCOME: No further action required

5.

ADVERTISER: Prairie Naturals

COMPLAINANT: Physician

SUBJECT: Cardio-Force detail material

PRECLEARANCE: No

ALLEGATIONS: Off-label promotion for treatment of Heart Disease

PAAB DECISION: Referred case to Health Canada as per their policy.

PAAB staff

Commissioner: Ray Chepesiuk
Senior Reviewer: John Wong
Reviewers: Colin Campbell
Pauline Dong
Lucia Kim
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?

Fédération des médecins spécialistes du Québec
Canada's Association for the Fifty-Plus (CARP)
Canadian Association of Medical Publishers
Canadian Drug Manufacturers Association
Canadian Medical Association
Canada's Research-Based Pharmaceutical Companies
Canadian Pharmacists Association
Consumers' Association of Canada
Association of Medical Advertising Agencies
Nonprescription Drug Manufacturers Association
Advertising Standards Canada

Chair	Dr. R. Perkin
Past Chair	Dr. J. Godden
Treasurer	L. Biondi

Health Canada is an ex-officio observer

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*
- *Review 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.*
- *Training, adjudicating complaints, administering penalties, reporting of infractions, and other activities to encourage compliance.*
- *Advising clients about Direct-to-Consumer Advertising regulations regarding prescription drugs*

For information or if you have comments:

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