Pharmaceutical Advertising Advisory Board **January 2002**

PAAB UPDATE

Quarterly Information Bulletin

PAAB
ACTIVITIES DURING THE
FOURTH QUARTER OF 2001

Year 2002 marks the 26th 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.

General Meeting Highlights

The PAAB General Meeting of Directors was held Friday, November 9, 2001 at the College of Family Physicians in Mississauga, Ontario. The next Annual/General Meeting will be held on April 12, 2002 from 9 a.m. to 1 p.m. at the same location.

- The fee schedule and budget for 2001 were approved.
- Commissioner Chepesiuk reported that the implementation of the Code revision regarding the use of published abstracts of oral and poster presentations as support for advertising claims had been implemented. The transition was fairly smooth. Therapeutic areas of concern expressed by advertising agencies were HIV, Oncology and Multiple Sclerosis. The Board reaffirmed its decision to allow no exemptions.
- Chair R. Perkin asked the industry to reflect on the combative nature that has arisen this year resulting in a higher than normal trade dispute number.
- In his report to the Board, Commissioner Chepesiuk noted that Health Canada could be more responsive to PAAB's request for their action in cases of noncompliance with PAAB decisions. It was also noted that there appeared to be a lack of Health Canada enforcement regarding infractions of federal advertising regulations by advertisers of natural health products. Many are making drug claims without Health Canada approval.
- The Board approved a Code revision intended to clarify the requirement for PAAB review of Patient Educational materials distributed through health professionals.
- Ann Sztuke-Fournier reported that no time frame has been set for the public consultation phase of the legislative review, including advertising regulations, that has been started. She also informed the Board members about a Health Canada sponsored workshop regarding "Communication of Drug Safety Information".

Fair Balance

It appears that everybody except people in advertising agencies and marketing departments understands and appreciates the fact that the approved indication and cautionary information is important information that should be presented in

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a clear and prominent manner. Please do not look for the lowest common denominator to present your information. 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. Health Canada has advised the 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. There is still a tendency of some pharmaceutical advertisers to either not include any safety information or to present it in small type footnotes in an obscure part of the advertising. The PAAB 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. 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.

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 a review fee for written opinions. Advertisers should note that the PAAB members have agreed to the Health Canada request that it be copied on final versions of submissions reviewed by the PAAB.

Faxed Advertising

We remind advertisers that faxed advertising communications to health professionals are 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) requires PAAB review and inclusion of prescribing information with the fax distribution.

Code Revision – Patient Education

At the November 9, 2001 Board Meeting the PAAB Directors approved the following Code revision.

> Section 6.6f will read as '*Patient Information direct from and consistent with the product monograph [see 6.4 for regulations]*'.
> Section 6.4 will read as '*Service-oriented vehicles are designed to contribute to the healthcare professional's/ patient's understanding of a condition or its treatment. Such materials include Educational APS and patient information [see 6.6f for exemptions] that are prepared or controlled by the manufacturer of its agent [11.10]…*'.
> Section 6.4.2 will read as '*Examples of patient information vehicles are company-controlled patient brochures, internet and other electronic presentations, and 1-800 number scripts.*'
> Newly created Section 6.4.3 will read as '*Company controlled or prepared patient information is information that contains editorial material that is in addition to the patient information section of the product monograph*'.

You should note that this is a clarification of the current wording to show the necessity of formal review of company created and/or controlled patient material distributed through health professionals. It does not cover items created under the full control of a third-party organization such as a patient advocacy association. The members agreed to an implementation date of April 1, 2002. We look forward to your full cooperation with the PAAB Code of Advertising Acceptance.

Review Activity

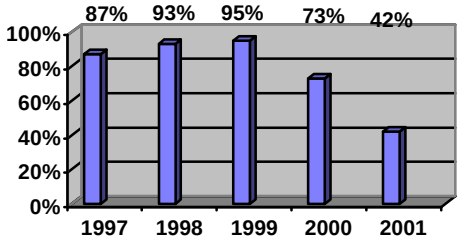
During the period of October 1 to December 31, 2001, the total number of human and veterinary drug advertising submissions reviewed was 718. This compared to 658 during the same period of 2000.

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

In 2001, the total number of submissions reviewed was 2745 compared to the 2000 total of 2662. This was the third highest submission review volume in the 25 year history of the PAAB.

During the fourth quarter of 2001, 40% 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. For all of 2001, the turnaround to first review in five days or less was 42%. This decrease from the record rate set in 1999 resulted from having fewer experienced reviewers, a workload more weighted towards detail material and some particularly combative advertisers. Year 2001 saw more than the average number of product launches and many in particularly competitive therapeutic areas. The PAAB Commissioner notes that arguing with the PAAB Reviewers about unacceptable claims and support material that most stakeholders view as unethical serves to slow down the review process. Based on the performance of previous years, the PAAB Reviewers should also work to improve this turnaround time statistic for 2002. For the first time, PAAB has six Reviewers.

Share of ads with first review in 1- 5 days



Review Volume History

Human Drug Advertising/Promotional Systems

1997	1998	1999	2000	2001
2540	2354	2742	2591	2687

Complaints History

Stage Two Decisions

1997	1998	1999	2000	2001
14	26	24	26	36

Monitoring History

Violation Notices Initiated by PAAB

1997	1998	1999	2000	2001
67	16	21	26	29

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 and unapproved products are sent without delay to Health Canada for investigation.

There are three 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: October 1 to December 31, 2001

During the period of October 1 to December 31, 2001, the PAAB Commissioner processed 5 **Stage 2 complaints**. PAAB reviewed 718 advertising pieces during the same period. This number brings the complaint total for 2001 to 36 (2745 product advertising reviews).

Of the 5 complaints, 2 were generated from advertising that had been previously PAAB-reviewed. Both complaints were rejected. Of the

3 complaints on advertising that were not PAAB-approved, all three were sustained. One was sent to Health Canada for opinion regarding a safety issue.

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 7 notice of violation letters in the fourth quarter bringing the total for the year to 29.

STAGE TWO DECISIONS

1.
ADVERTISER: Pharmacia

COMPLAINANT: Boehringer-Ingelheim

SUBJECT: c01-71 Stat-Fax letter promoting Celebrex (celecoxib) safety claims

PRECLEARANCE: No

ALLEGATIONS: Promotional item requires PAAB preclearance (s6.2) and should not be signed by medical personnel. Pharmacia counters that this was exempt because it was a safety issue involving Health Canada, not a promotional item (s6.6.c).

PAAB DECISION: On October 20, 2001, I requested an opinion from Health Canada if they considered this item to be a safety issue or advertising. No response was received by the end of December.

2.
ADVERTISER: Wyeth-Ayerst

COMPLAINANT: Berlex

SUBJECT: c01-74 Alesse (levonorgestrel-ethinyl estradiol) advertisement in SOGC journal

PRECLEARANCE: Yes

ALLEGATIONS: Alleges off-label claims promoting Alesse to treat acne and reduce weight gain(s3.1)

PAAB DECISION: Rejected. Ad is actually discussing side effects of OC's and the effect of Alesse in causing acne or weight gain, not promoting off-label claims.

3.
ADVERTISER: Novartis

COMPLAINANT: GlaxoSmithKline

SUBJECT: c01-79 Patient Education Post-it note distributed through health professionals.

PRECLEARANCE: No

ALLEGATIONS: Branded service item requires PAAB preclearance review (s6.4), is missing pertinent safety information (s2.4) and the complete indication (s2.1), and the information is difficult to read (s7.2.1).

PAAB DECISION: Sustained. Agree with complainant on all aspects of the complaint.

PENALTY: Novartis should cease distribution. It should be noted that this ruling was made prior to the Board revising section 6.4 to provide clarification for sponsors.

OUTCOME: Novartis agrees with PAAB ruling.

4.
ADVERTISER: Janssen-Ortho

COMPLAINANT: Pharmacia

SUBJECT: c01-80 Ditropan XL (oxybutynin chloride) journal ad

PRECLEARANCE: Yes

ALLEGATIONS: 1. comparative claim is based on one study that is not in the product monograph and there is inadequate disclosure of study parameters. 2. There is an overstatement of efficacy "consistent reductions in urge incontinence episodes of 83% to 90%" and the

layout is misleading. The U. S. FDA has rejected some of the study information.

PAAB DECISION: Rejected. 1. The comparative claim is valid because it is a restricted claim based on one study that shows all the necessary study parameters. Code s5.8 allows for use of studies not in the product monograph as support for claims that are in the product monograph. 2. The efficacy claim is based on four studies that were included in the Health Canada approved product monograph. U.S. FDA rulings have no direct bearing in Canada unless corroborated by Health Canada. We agree that the layout could be improved but it is not currently overtly misleading.

5.

ADVERTISER: Janssen-Ortho

COMPLAINANT: Wyeth-Ayerst

SUBJECT: c01-86 Company generated Editorial Report "Symposium on Contraceptive and Reproductive Health"

PRECLEARANCE: Yes but expired.

ALLEGATIONS: Comparative superiority statements are made by the physician writers based on lab work and not comparative clinical trials. Intent is to imply that levonorgestrel brands are not as effective as other Ocs by extrapolation from non-clinical data.

PAAB DECISION: Sustained. Agree that conclusion statements made by the authors are not well supported by comparative.clinical evidence. Item was originally approved in the s7.8 editorial category because it provided new information about the OC category. However, the conclusions were not looked at in the context of the new information being non-clinical.

PENALTY: Cease distribution. Remove existing copies from the sales representatives and they should nbot refer to the questioned information during their physician calls.

OUTCOME: Janssen-Ortho agrees with the remedial action.

PAAB

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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.

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

- *Distinction of Advertising and Other Activities*
- *Overview of Drug Advertising*
- *PAAB and Therapeutics Products Directorate Roles and Consultation re Advertising Review*

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)
Fédération des médecins spécialistes du Québec (FMSQ)
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