Pharmaceutical Advertising Advisory Board **January 2003**

PAAB UPDATE

Quarterly Information Bulletin

PAAB
ACTIVITIES DURING THE
FOURTH QUARTER OF 2002

Year 2003 marks the 27th operating year of 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.

PAAB Meetings

January 17, 2003 – Annual/General Meeting and Strategic Planning Session

February 13, 2003 – Executive Committee

What is drug "advertising" ?

This is a reminder that the definition of *advertising* in the Food & Drugs Act is "any representation by any means whatever for the purpose of promoting directly or indirectly the sale or disposal of any food, drug, cosmetic or device". Therefore, most product-focussed messages would be considered *advertising*. Keep that definition in mind when you are creating communications to health professionals or to the public. That includes items that are called "patient information" or "educational" letters or reports and distribution of third-party communications by drug manufacturers.

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 therapeutic and/or product claims (economic, QOL, merit) requires PAAB review and inclusion of prescribing information with the fax distribution.

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.

LOOK INSIDE

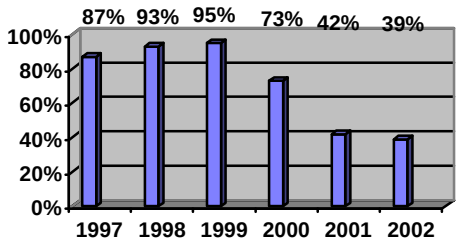
Review Activity

During the period of October 1 to December 31, 2002, the total number of first review submissions reviewed was 842. This compared to 720 during the same period of 2001.

In 2002, the total number of submissions reviewed was 3224 compared to the 2001 total of 2745. This was the highest submission review volume in the 26 year history of the PAAB. The first reviews were done primarily by five Reviewers. All of the PAAB staff should be commended for an extraordinary performance in 2002.

During the fourth quarter of 2002, 41% of the submissions were given a first review response in five days or less and 97% were given a first review response in 10 days or less. For all of 2002, the turnaround to first review in five days or less was 39%. Year 2002 saw many product launches in competitive therapeutic areas. There were increases in every category. The Reviewers faced a workload more weighted towards detail material (46%) and some particularly combative advertisers. The PAAB Commissioner advises advertisers 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. Also slowing down the process was the fact that clients were inconsistent in the submission of material, often submitting material that had been previously rejected by the PAAB or that had insufficient regulatory or scientific support. The element of trust diminishes when this occurs.

Share of ads with first review in 1- 5 days



Review Volume History

Human Drug Advertising/Promotional Systems

1997	1998	1999	2000	2001	2002
2540	2354	2742	2591	2687	3217

Complaints History

Stage Two Decisions

1997	1998	1999	2000	2001	2002
14	26	24	26	36	30

Monitoring History

Violation Notices Initiated by PAAB

1997	1998	1999	2000	2001	2002
67	16	21	26	29	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, 2002

During the period of October 1 to December 31, 2002, the PAAB Commissioner processed 12 **Stage 2 complaints**. PAAB reviewed 842 advertising pieces during the same period. This number brings the complaint total for 2002 to 30 (3224 product advertising reviews).

Of the 12 complaints, 3 were generated from advertising that had been previously PAAB-reviewed and all 3 complaints were rejected. Of the 9 complaints on advertising that were not PAAB-approved, all 9 were sustained.

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 11 notice of violation letters in the fourth quarter bringing the total for the year to 29. Three cases were sent to Health Canada.

STAGE TWO DECISIONS

1.
ADVERTISER: AstraZeneca

COMPLAINANT: Abbott

SUBJECT: c02-51 Nexium (esomeprazole) #DPLA1201 Detail aid

PRECLEARANCE: Yes

ALLEGATIONS: s3.1.5, 4.1.1 and 4.1.2 – re misleading data presentation. Comparative intragastric pH control charts from the Nexium product monograph (PM) were arranged in a different order from how they appeared in the PM.

PAAB DECISION: Rejected. Re-arrangement of charts did not make the data presentation misleading

PENALTY: Assessed Abbott with $500 fee.

2.
ADVERTISER: Bristol Myers Squibb

COMPLAINANT: Novartis

SUBJECT: c02-57 various Avapro (irbesartan) APS

PRECLEARANCE: Yes

ALLEGATIONS: Statement "Avapro is the #1 recommended ARB for the treatment of essential hypertension and diabetes" based on IMS Canadian Disease and Therapeutic index (CDTI) is not statistically valid (s5.10) and it is not within the current Avapro Product Monograph indications (s3.1)

PAAB DECISION: Rejected. Consultation with IMS reveals the CDTI measurement tool has been used by many companies and is considered robust to support the Avapro statement "recommended". IMS confirmed that their measurement was recommended use for treatment of hypertension in hypertensive patients with concomitant diabetes. Therefore, BMS was not promoting off-label.

PENALTY: Assessed Novartis with $500 fee.

3.
ADVERTISER: Abbott

COMPLAINANT: Janssen-Ortho

SUBJECT: c02-61 Prevacid (lansoprazole) patient information in sample kit

PRECLEARANCE: No

ALLEGATIONS: Should be precleared by the PAAB and statements that appear to equate heartburn with reflux with GERD are misleading and not representative of the Prevacid PM. Comparative presentation is misleading.

PAAB DECISION: Sustained. Item should be precleared by the PAAB and indication issues would be handled during preclearance review.

PENALTY: Cease distribution. Companies are still learning about patient information review requirements.

OUTCOME: No objection stated.

4.
ADVERTISER: Oryx

COMPLAINANT: private physician who requested anonymity

SUBJECT: c02-64 FXT-40 (fluoxetine) advertising on giveaway items, plastic light bulb filled with congealed jelly beans, post-it notes, and glass figurine

PRECLEARANCE: No

ALLEGATIONS: violation of PAAB Code section 2.8 because the gifts to physicians contradicted Canadian Medical Association policy

PAAB DECISION: sustained. Oryx should respect health professionals' Codes of Conduct and ethics.

PENALTY: Cease distribution of the gimmicky gifts

OUTCOME: Oryx President disagreed with the PAAB ruling. The PAAB Commissioner requested and received intervention by the CMA Secretary-General to advise Oryx regarding CMA policy. PAAB received no correspondence from Oryx after the CMA letter to Oryx.

5.
ADVERTISER: AstraZeneca

COMPLAINANT: GlaxoSmithKline

SUBJECT: c02-67 Zomig (zolmitriptan) Detail Aid

PRECLEARANCE: Yes (originally June 2001)

ALLEGATIONS: Detail Aid misstates drug interaction with fluvoxamine

PAAB DECISION: Rejected. The Zomig Product Monograph states "appropriate observation" for all SSRIs and a possible dosage adjustment for fluvoxamine. The APS stated "appropriate observation" and therefore is not overtly misleading.

PENALTY: assessed GSK with $500 fee.

6.
ADVERTISER: AstraZeneca

COMPLAINANT: GlaxoSmithKline & Merck Frosst in separate complaints

SUBJECT: c02- 67 "Educational" piece "2002 Clinicians Guide on Managing Primary Headache".

PRECLEARANCE: No
ALLEGATIONS: Code sections 2.1, 3.1, 5.10, 5.11 and 5.7 Item is advertising subject to PAAB preclearance review. Promotion of off-label indications for Zomig is misleading. Comparative side effect and efficacy data presentation is potentially misleading. Undisclosed study parameters.

PAAB DECISION: Sustained. Item is "advertising" with multiple PAAB Code violations.

PENALTY: Cease distribution. Rx&D notified.

OUTCOME: AstraZeneca agreed to cease distribution and destroy undistributed copies.

7.
ADVERTISER: Biogen

COMPLAINANT: Serono

SUBJECT: Avonex (interferon-beta) "educational" piece entitled "MD Newswire" about neutralizing antibodies

PRECLEARANCE: No

ALLEGATIONS: Item was "advertising" subject to PAAB preclearance review (s6.2), statements were not supported by the Avonex Product Monograph, based on an oral presentation at a meeting (3.1) , and based on a study with defective methodology

PAAB DECISION: Sustained. Item is advertising (s6.2) and would not be acceptable to PAAB Code section 3.1. Consultation with Health Canada reveals subject data of the letter should be reviewed by Health Canada for inclusion in the product monograph.

PENALTY: This appears to be a repeat violation involving similar claims (see c02-26). A correction letter was requested.

OUTCOME: Biogen agreed to send a correction letter in December 2002 subject to review by the PAAB.

8.
ADVERTISER: Ferring

COMPLAINANT: Axcan

SUBJECT: c02-75 Pentasa Patient Information

PRECLEARANCE: No

ALLEGATIONS: Item should be precleared and information is not consistent with the Product Monograph

PAAB DECISION: Sustained. This was a piece created in 2001 and did not require PAAB review at that time. Item does not meet Health Canada policy for either patient information or consumer brochure. It is a combination of Pentasa specific information, promotional elements and comparative copy. PAAB should be asked to review this item and advise Ferring of regulatory requirements.

PENALTY: Cease distribution and destroy remaining copies.

OUTCOME: Ferring disagreed with ruling but after discussion with the PAAB Commissioner about referral to Health Canada for non-compliance, Ferring agreed to cease distribution by January 31, 2003.

9.
ADVERTISER: Janssen-Ortho

COMPLAINANT: Solvay

SUBJECT: c02-77 Pariet (rabeprazole) 3 giveaway items

PRECLEARANCE: No

ALLEGATIONS: advertising on reprint folder, fridge magnet and notepad was not PAAB –reviewed (s6.4)

PAAB DECISION: Sustained. Items contain product-focussed promotional statements that constitute "advertising" and are subject to PAAB review (s1 & s6.4)

PENALTY: cease distribution and retrieve items from sales force. Rx&D notified.

OUTCOME: waiting reply as of December 24, 2002.

10.
ADVERTISER: Janssen-Ortho

COMPLAINANT: Solvay

SUBJECT: c02-78 Pariet (rabeprazole) promotional Items: "Phamacy Bulletin board, study abstracts

PRECLEARANCE: No

ALLEGATIONS: Advertising in Pharmacy Bulletin Board has product-focussed Pariet claims and should be PAAB-reviewed. Distribution of abstracts for promotional purposes violates PAAB Code section 3.1

PAAB DECISION: Sustained. Fax services have been viewed as a loop-hole for promotion of claims that PAAB would not accept. Advertisers should encourage publishers of these fax messages to support the advertising standards in the PAAB Code.

PENALTY: Cease further distribution and notice sent to Rx&D

OUTCOME: waiting reply as of December 24, 2002.

11.
ADVERTISER: Janssen-Ortho

COMPLAINANT: Eli Lilly & a private physician (in separate letters)

SUBJECT: c02-79 "educational" letter sent with the letterhead of a private physician

PRECLEARANCE: No

ALLEGATIONS: Letter was deceptive in that the financial involvement of Janssen-Ortho was not disclosed and the letter was promotional in nature, subject to review requirements of the PAAB Code. The product comparisons were not fair and balanced.

PAAB DECISION: Sustained. Item was promotional in nature and should have stated Janssen-Ortho involvement, been precleared by the PAAB to eliminate the unfair attack on a competitor.

PENALTY: Correction letter requested.

OUTCOME: After PAAB review, a correction letter was sent to the same target audience as the original

12.
ADVERTISER: Amgen

COMPLAINANT: Ortho Biotech

SUBJECT: c02-65 promotional letter for Aranesp (darbepoetin alfa)

PRECLEARANCE: No

ALLEGATIONS: Amgen USA sent an "Educational" letter to Canadian physicians with comparative information about Eprex (epoetin alfa) and Aranesp re Pure Red Cell Aplasia. Statements about Aranesp were not consistent with the Product Monograph and the letter was an unfair comparison to Eprex. The letter was promotional and should have bbeen precleared by the PAAB.

PAAB DECISION: Sustained. We agreed with the OrthoBiotech allegations. Ortho Biotech had also complained to Health Canada and Health Canada copied the PAAB on their letter to Amgen.

PENALTY: Correction letter to same target audience requested. Rx&D notified.

OUTCOME: Amgen filed for Stage Three Appeal. The hearing is scheduled for January 15, 2003.

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
Treasurer	Lorenzo Biondi

Health Canada is an ex-officio observer

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*

PAAB
CCPP