Pharmaceutical Advertising Advisory Board **July 1999**

PAAB UPDATE

REPORT ON FIRST HALF OF 1999

Comparative claims standards improved

On January 1, 1999, PAAB reviewers implemented the revised Code Section 5 *Comparative Claims* to incorporate the principles for comparative drug advertising set by Health Canada.

The revised section helps to clarify what data is required to support comparative claims. Since 1995, PAAB reviewers' practice has been to require peer-reviewed, head-to-head trials in support of comparative claims of safety and efficacy. Clearer Code wording should send a signal to advertisers to improve the quality of ad submissions.

PAAB will continue to accept 'restricted' claims based on the presentation of data from one comparative study but extrapolation of the claim beyond the actual conditions of the supporting studies is not acceptable.

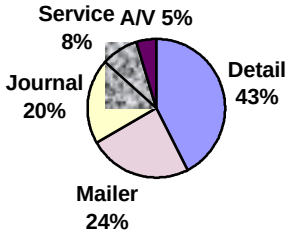
PAAB Commissioner Ray Chepesiuk reports that the industry has been generally cooperative during the implementation of these revised standards. He says that the next challenge will be to get industry advertisers to understand the proper presentation of relative risk claims and the proper use of equivalence claims in advertising.

Chepesiuk appointed Commissioner

Effective May 1, 1999 the PAAB appointed Ray Chepesiuk to be Commissioner. Chepesiuk had been Interim Commissioner since the departure of former Commissioner Mark McElwain on November 1, 1998. He had been Deputy Commissioner at PAAB since 1990.

Near record number of submissions

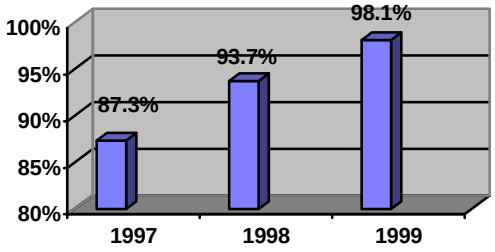
During the first six months of 1999, the PAAB staff were kept busy reviewing a near-record number of submission files. The total number of submissions reviewed was 1357, only 11 short of the previous high set in 1993.



The proportion of advertising vehicles that were submitted for review was similar to 1998.

The review staff of Senior Reviewer Jane Shum, Colin Campbell, Joanna Rizos and John Wong performed well in handling the heavy volume. The turnaround time actually exceeded the high standard set in 1998.

Share of ads reviewed < 5 days



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 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.*

During the first six months of 1999, the PAAB Commissioner processed 9 Stage 2 **complaints**. This number contrasts to 26 in all of 1998. There was also 1 Stage 3 appeal panel ruling. PAAB reviewed 1357 advertising pieces during the first six months of 1999.

Of the 9 complaints, 7 were generated from advertising that had been previously PAAB-reviewed; 4 of these complaints resulted in withdrawal of PAAB's previous acceptance and 3 complaints were rejected. One of these complaints was referred to PAAB by the Therapeutic Products Program of the Health Protection Branch (HPB). Under the program's policy, the PAAB Code process is the initial avenue for complaint resolution, even for advertising not sent initially to PAAB for review. The 2 complaints on advertising that were not PAAB-approved were sustained.

During 1999, PAAB continued to regularly **monitor** journals, the Internet, and receive direct-mail/detail aid materials collected by health professionals as part of its monitoring program. In the past year, a total of 14 monitoring letters was sent, most relating to unreviewed advertising materials containing misleading or off-label claims, lack of balancing risk/benefit information, or the absence of detailed prescribing information. All of these ads were either withdrawn or resubmitted for PAAB review. When warranted, cases are referred to the respective trade associations for appropriate action and/or reported to Health Canada in accordance with the PAAB Code.

PAAB COMPLAINT REPORT
Period: January 1, 1999 to June 30, 1999

STAGE TWO DECISIONS

1.

ADVERTISER: Astra Canada

COMPLAINANT: Abbott Canada (referred by Health Canada)

SUBJECT: c99-03 - ^{Pr}Losec (omeprazole) 1-2-3 campaign advertising in journals, detail aids, file card, display panel, sticker.

PRECLEARANCE: Yes

ALLEGATIONS:
Six allegations related to " by directing physicians to write prescriptions in abbreviated form, these advertisements (1) compromise the safety of patients and fail to promote credibility and trust (contrary to PAAB Code, Section 2.1); (2) neither reflect an attitude of caution nor provide sufficient information to permit assessment of risk/benefit

(contrary to PAAB Code, Section 2.4); and (3) present an imminent and significant health hazard. The advertisements refer to "the approved" Losec triple therapy, yet neither LOSEC 1-2-3 A nor LOSEC 1-2-3 M are approved drugs with drug identification numbers (DINs).and thus contravene the Food *and Drugs Act* and Regulations. Advertisements encouraging incomplete prescriptions are contrary to PAAB Code, Section 7.1. Furthermore, pharmacists would appear to be prohibited by the *Food and Drugs Act* and Regulations from dispensing or selling the drugs pursuant to such incomplete prescriptions."

PAAB DECISION:
The alleged infraction of code section 7.1 is not upheld because we are aware that prescribing information did accompany the distribution of these APS. Abbott has not provided evidence that these advertisements compromise patient safety, fails to promote credibility and trust (2.1), do not reflect an attitude of caution, do not provide sufficient information to permit assessment of risk/benefit (2.4) and present an imminent and significant health hazard. With respect to the Code requirement 2.4, the APS contains sufficient balancing safety information to meet the technical requirements for the standard set by PAAB. Astra has shown letters of support that doctors organizations do support the program and will encourage physicians to write prescriptions in this manner. Abbott is incorrect in its assertion that the dosage regimen has not been approved by Health Canada. It is clearly stated in the the Health Canada approved Losec product monograph. Abbott is incorrect in their assertion that this practice would result in an "incomplete prescription". Also, we point out to Abbott that the writing and dispensing of prescriptions is subject to provincial statutes. Astra has met federal requirements with respect to the promotion of this dosage regimen. There appears to be some split opinion among the provincial pharmacy regulatory bodies on the acceptability of this marketing practice. Astra has provided letters of support from two physician organizations. It is not the role of PAAB to decide on the appropriateness of provincial regulations. Nationally, there is no consensus opposed to this practice. Abbott has provided no evidence that patient safety has been compromised by this marketing practice.
At this time, the allegations put forth by Abbott, about the compromise of patient safety due to this marketing practice, have not been substantiated with evidence. It appears to be mere speculation as no proof of irreparable harm has been shown. Astra appears to have been responsible in their action of putting into place an extensive educational program to support the introduction of this marketing practice. Therefore, this complaint is not sustained by the PAAB. There is no further action required of Astra with respect to Stage 2 of this complaint.

PENALTY: Complaint rejected, therefore no penalty. Abbott was invoiced $500 for the registration fee.

OUTCOME: Abbott filed Stage 3 Appeal

2.
ADVERTISER: Novartis

COMPLAINANT: Janssen-Ortho

SUBJECT: c99-04 - ^{Pr}Lamisil (terbinifine) single sponsor journal

PRECLEARANCE: No

ALLEGATIONS: Section 1, not submitted to PAAB for review; sections 5.2 and 5.6, unsubsubstantiated claims comparative to Sporanox (itraconazole) that comprise an unfair attack

PAAB DECISION: Sustained for Janssen-Ortho - It is advertising subject to PAAB Code and should be submitted for PAAB review prior to further dissemination.

PENALTY: Novartis claims there was limited distribution. Therefore, immediate cessation of distribution is deemed to be sufficient penalty.

OUTCOME: Novartis and Janssen-Ortho agree with ruling.

3.
ADVERTISER: Merck-Frosst

COMPLAINANT: Dr. Joel Lexchin

SUBJECT: c99-05 - Varivax (varicella virus vaccine, live, attenuated) journal ad

PRECLEARANCE: Yes

ALLEGATIONS: Section 4.1 infraction; Emphasis in copy and graphics imply a proven claim that overall mortality is reduced by immunization with Varivax when in fact the claim has not been proven. He suggests that a disclaimer would be needed to prevent the misleading claim.

PAAB DECISION: Sustained for Dr. Lexchin - Agree with complainant that the implied claim is not seen within the Health Canada approved product monograph.

PENALTY: Cease distribution of ad.

OUTCOME: Merck-Frosst agreed to cease distribution of journal ad and revised it with a disclaimer.

4.
ADVERTISER: Hoffmann-LaRoche

COMPLAINANT: Crystaal Corporation

SUBJECT: c99-07 – Activase (alteplase) detail aid

PRECLEARANCE: Yes

ALLEGATIONS: Section 2.3 violation; context of claims misrepresents GUSTO III study in that Roche had omitted secondary finding data and more safety data related to bleeding

PAAB DECISION: Sustained for Crystaal.

PENALTY: Cease distribution.

OUTCOME: Roche agreed to cease distribution and sent revised copy for PAAB review and approval.

5.
ADVERTISER: SmithKline Beecham

COMPLAINANT: Glaxo-Wellcome

SUBJECT: c99-09 - [Pr]Kytril (granisetron) direct mail to physicians

PRECLEARANCE: Yes

ALLEGATIONS: Sections 5.2 and 5.6 violations - Statements are unbalanced and unfairly represent the comparative dosing between Kytril and Zofran and selected studies are referenced.

PAAB DECISION: Rejected - Main message of the letter is that there is new pricing for Kytril The comparative claim versus Zofran is within product monograph limitations and the SB studies are peer-reviewed, published and are more recent than the studies mentioned by Glaxo-Wellcome. Therefore, the allegations are rejected.

PENALTY: Rejected, therefore no penalty. Glaxo-Wellcome was invoiced $500 for the registration fee.

OUTCOME: No action required of SmithKline Beecham.

6.
ADVERTISER: Zeneca

COMPLAINANT: Merck-Frosst

SUBJECT: c99-10 - [Pr]Accolate Detail Aid

PRECLEARANCE: Yes

ALLEGATIONS: Headline goes beyond indication; claims are not consistent with consensus guidelines; adjunctive claim is not within product monograph.

PAAB DECISION: Rejected. Claims appear to be within the restrictions set by the product monograph and consistent with consensus opinion.

PENALTY: Rejected, therefore no penalty. Merck-Frosst was invoiced $500 for the registration fee.

OUTCOME: No action required of Zeneca.

7.
ADVERTISER: Alcon

COMPLAINANT: CIBAVision

SUBJECT: c99-21 – [Pr]Emadine (emadastine difumarate ophthalmic solution) physician letter, CPS Insert and Detail Aid

PRECLEARANCE: No

ALLEGATIONS: Section 5.3 violation for superlative claim “The Ultrafast Antihistamine” not acceptable in the context of comparative claims to Livostin; section 5.2 violation – comparative

claims were not supported by adequate evidence. Seasonality was an important factor for this therapeutic area (treatment of allergies), therefore great harm could be achieved by Alcon during their launch.

PAAB DECISION: Sustained for CIBAVision. PAAB had reviewed and accepted an Emadine journal ad with which CIBAVision found no fault. Several of the allegations were related to claims rejected by PAAB during the journal ad review.

PENALTY: Alcon should immediately cease distribution of the APS in violation of the PAAB Code. They should distribute corrected versions within 30 days to the same audience as the original material. The letter should state that the revised letter was sent at the request of PAAB.

OUTCOME: Alcon complied with the three components of the corrective action requested by PAAB.

8.
ADVERTISER: Searle/Pfizer

COMPLAINANT: McNeil Consumer

SUBJECT: c99-25 – [Pr]Celebrex (celecoxib) physician letter

PRECLEARANCE: Yes

ALLEGATIONS: Section 2.4 violation – claim of "excellent safety profile" was not substantiated and drug interactions were not accurately conveyed.

PAAB DECISION: Rejected allegation about "excellent safety profile" because it appeared to be supported by the product monograph and published medical opinion. Sustained allegation about drug interactions because of new information that had arisen since the the initial PAAB review at launch.

PENALTY: Cease distribution of all APS with similar drug interaction claims and send revised copy for PAAB review.

OUTCOME: Searle/Pfizer agreed to revise materials to reflect current information about drug interactions.

9.
ADVERTISER: Janssen-Ortho

COMPLAINANT: Pfizer

SUBJECT: c99-27 - [Rx]Muse (alprostadil) general
press release, journal ad, and patient information sheet.

PRECLEARANCE: Yes

ALLEGATIONS: Section 1 violation – general press release was not PAAB reviewed; Sections 2.1, 3.1, 2.4, 3.5, 2.3, 4.2, 4.3 violations in journal ad related to misleading claims about drug interactions, concomitant conditions, and selected data claims related to in-clinic or at home data. Sections 2.1, 2.4, 3.1 violations in patient information sheet related to claims of "easy use", adverse events, "simple dosing", and a wording omission for safety balance.

PAAB DECISION: General press releases do not fall under the scope of PAAB review. Allegations about the journal ad claims did not have sufficient merit to require immediate change although PAAB reviewers were alerted to two examples. The patient information was reviewed by PAAB even though Janssen-Ortho had the option not to send it to PAAB and it was found to be balanced and supported in an adequate manner.

PENALTY: No penalty. Pfizer was invoiced $500 for the registration fee.

OUTCOME: No action required of Janssen-Ortho.

STAGE 3 DECISIONS

These are Stage 2 decisions that are appealed and then heard by an independent 3 member panel. See Code section 9.7.

1.

ADVERTISER: Astra
COMPLAINANT: Abbott
SUBJECT: c99-03 - Losec (omeprazole) journal ad, posters, detail aid
PRECLEARANCE: Yes

ALLEGATIONS:
Astra developed a drug prescribing program as a registered trademark which does not qualify for pharmaceutical product status according to PAAB's code and is not supported by applicable federal and provincial laws. 2. The use of LOSEC 1-2-3A and LOSEC 1-2-3M in place of a fully written prescription has led to confusion and could lead to errors among health care professionals. The use of LOSEC 1-2-3A and LOSEC 1-2-3M as currently promoted by Astra, does not reflect accurate, complete and clear promotion.

PANEL DECISION:
The advertisement in question does make a claim for Losec and is, therefore, within the mandate of PAAB. The advertisement in question advertises Losec. There is no obvious contravention of applicable federal and provincial laws in the view of the Panel. The Panel does recognize that there does seem to be some controversy here. In the Panel's opinion, PAAB and this Panel does not have the mandate or skills required to resolve this. In the advertisement in question, physicians were instructed to use a trademark to write a prescription before there was any link to the trademark in the Product Monograph. In our opinion this is not clear promotion, and could have led to confusion. In this instance, the trademark use in the advertisement is of such significance that it should have been in the Product Monograph before the promotional program was approved.

PENALTY:
There is no reason to withdraw, cease or retract all activities now because the trademark is included in the January 25, 1999 version of the Product Monograph. The Panel believes that all prescribing information accompanying advertisements of LOSEC must reflect the current version of the Product Monograph. The Panel decided that the $2500 penalty should be borne by Astra. Astra should more formally (i.e. in writing) contact the Colleges of Physicians to seek their endorsement of the prescribing program. Astra should work with the Colleges to monitor that prescriptions written for LOSEC 123-A and 123-M are dispensed appropriately, including the assurance that potential drug interactions are caught. Astra should work with the Colleges to continue to ensure that the components of LOSEC 123-A 123-M are understood by pharmacists and physicians. The Panel also recommends that Abbott do the same with Hp-PAC.

OUTCOME: Astra and Abbott accepted the decision of the panel.

Who makes up the "Board" in PAAB?

Voting Organizations

Advertising Standards Canada
Association des médecins de langue française du Canada
Association of Medical Advertising Agencies
Canada's Research-Based Pharmaceutical Companies
Canadian Association of Medical Publishers
Canadian Drug Manufacturers Association
Canadian Medical Association
Canadian Pharmacists Association
Consumers' Association of Canada
Nonprescription Drug Manufacturers Association

Voting Individuals

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

Health Canada is an ex-officio observer

Executive Committee

Chair	Dr. Reg Perkin
Vice-Chair	Edward Stapor
Treasurer	Phil Diamond
Member	Gloria Bowes
Member	Gregory Hines
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*
- *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 of Advertising and Other Activities*
- *Overview of Drug Advertising*
- *PAAB and Drugs Directorate Roles and Consultation re Advertising Review*