Pharmaceutical Advertising Advisory Board **October 2003**

PAAB UPDATE

Quarterly Information Bulletin

PAAB
ACTIVITIES DURING THE
THIRD QUARTER OF 2003

Year 2003 marks the 27th 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

November 5, 2003 – Executive Committee
November 27, 2003 – General Meeting

Avoid Deception

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. Accredited CME material may be exempt from PAAB review but could be considered "advertising", and subject to PAAB Code provisions, depending on the content and manner of distribution if linked to a sponsor.

Manufacturers should look to improving the overall image of the pharmaceutical industry by providing promotional material that meets all of the legal and ethical requirements. The PAAB can you help you do that through the preclearance review process.

Safety First

It still amazes the PAAB Commissioner that too many agencies and advertisers do not understand the basis for the requirement of PAAB Code section 2.4. Section 2.4 states "APS must reflect an attitude of caution with respect to drug usage, with emphasis on rational drug therapy. The advertising copy should provide sufficient information to permit assessment of risk and benefit." If you see a need for prominence and frequency of a benefit message, then there is the same need for prominence and frequency of the risk information. The Reviewers are telling me of frequent examples regarding the difficulty they have to get clients to change copy to incorporate appropriate fair balance copy. For example, it took one agency four attempts to increase the type size on a four foot poster and that delayed the approval considerably. They had all of the fair balance copy in about four inches of space and you could not read it from a reasonable distance.

In my opinion some clients do not have sufficient training in health care to appreciate the concern that patients and health care professionals have about this information. The Commissioner has had to intervene during the review process to tell some clients that their approach is unacceptable. Clients

LOOK INSIDE

should be aware of a 2001 public inquest in Ontario regarding the death of a teenager. The recommendations included several regarding the dissemination of safety information regarding the correct use of a medication in promotional material.

The PAAB Reviewers appear to waste a lot of valuable reviewing time pleading with advertisers to adjust their fair balance. Please build the requirements of section 2.4 into the planning and creative phase.

Deputy Commissioner Appointed

As of September 1, John Wong was appointed PAAB Deputy Commissioner. This is in addition to his duties as Senior Reviewer. The position acknowledges John's experience and ability to contribute to attainment of the PAAB goals. Clients can seek advice form John about issues related to specific PAAB reviews.

Are You A PAAB Reviewer?

The PAAB is seeking a bilingual person to be a PAAB Reviewer. You should have a good knowledge of pharmacology and therapeutics as a starting point. Formal training will take care of the rest. Contact Commissioner Ray Chepesiuk at commish@paab.ca.

New PAAB Training Initiative

The PAAB Executive Committee has accepted a proposal from Pharmahorizons to partner in the creation of several mechanisms to provide pharmaceutical industry personnel with training regarding the PAAB Code of Advertising Acceptance. The goal is to teach the application of the PAAB code to new pharmaceutical industry employees. Pharmahorizons will provide professional logistical support while the PAAB staff will provide and maintain control of all content. Three approaches are anticipated: PAAB workshops, Internet interactive learning and PAAB staff participation in other Pharmahorizons training courses for new marketing personnel. The first offering of this workshop will be January 27, 2004 in Montreal and January 29 in Toronto. You can contact Pharmahorizons (1-888-514-5858) for more information.

Get DTCARx 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.

Review Activity

During the period of July 1 to September 30, 2003, the total number of first review submissions reviewed was 861. This compared to 804 during the same period of 2002, a 7% increase. From January 1 to September 30, 2003 there were 2674 first reviews compared to 2384 during the same period in 2002, a 12% increase.

During the third quarter of 2003, 21% of the submissions were given a first review response in five days or less and 84% were given a first review response in 10 days or less. The increased delay was due to the high volume and vacation time. The Reviewers faced a workload more weighted towards detail material at 51%. Next highest was mailers at 16%.

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 with agreement by all parties.*

PAAB COMPLAINT REPORT

Period: July 1 to September 30, 2003

During the period of July 1 to September 30, 2003, the PAAB Commissioner processed 2 **Stage 2 complaints**. PAAB reviewed 861 advertising pieces during the same period.

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 4 notice of violation letters on web-sites in the third quarter. Three cases were sent directly to Health Canada because they involved allegations regarding Direct-to-Consumer drug advertising.

STAGE TWO DECISIONS

1.
ADVERTISER: Merck Frosst

COMPLAINANT: GlaxoSmithKline

SUBJECT: C03-17 Maxalt Detail Aid

PRECLEARANCE: Yes - accepted November 2002

ALLEGATIONS: Contravention of s4.2.3 in that the relative risk reduction numbers were overemphasized in the context of this presentation as compared to the absolute numbers.

PAAB DECISION: Commissioner agreed with complainant that the context of the presentation could be improved to remove the emphasis on the relative risk.

PENALTY: Cease distribution of the APS immediately.

OUTCOME: Merck Frosst cooperated with the PAAB decision. PAAB Reviewers were reminded to not accept overemphasis on relative risk data.

2.
ADVERTISER: Teva Neuroscience

COMPLAINANT: Serono

SUBJECT: Journal Ad

PRECLEARANCE: Yes – accepted January 2003

ALLEGATIONS:
1. S 2.1, 4.1 - Misleading data claim "sustained mean relapse rate reduction – 29% demonstrated at two years" does not appear in the PM.
2. S3.1 - Claim not consistent with the product monograph "Copaxone reduced development of persistent black holes by 50%".
3. S3.1 – "Copaxone is indicated for Relapsing-Remitting Multiple Sclerosis".

PAAB DECISION:
1. The data in the PM appeared to be a different statistical analysis than the data that appeared in the APS. The APS was accurate in representing the data that appeared in the 1995 published study as a covariate adjusted mean and the data that appeared in the PM was the same data based on a 1998 published rework of the data given as a baseline adjusted mean. Health Canada had approved an efficacy indication based on this study and therefore it was not seen to be overtly misleading. While the Commissioner disagreed with the complainant he decided the presentation of the data could be improved by presenting both statistical analyses.

2 Consultation with Health Canada revealed that this claim would have to be submitted for Health Canada review and approval as an indication. Agree with complainant.

3 It appeared that over-editing of this APS omitted limitation copy that had appeared in previous Copaxone APS. Teva should include the full indication.

PENALTY: Withdraw PAAB acceptance and Teva to cease distribution of the journal ad.

OUTCOME: TEVA agreed with the ruling.

Voting Organizations
Canadian Medical Association (CMA)
Canadian Pharmacists Association (CPhA)
Canada's Research-Based Pharmaceutical Companies (Rx&D)
Canadian Generic Pharmaceutical 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*

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