PAAB REVIEW

Year 2005 marks the 29th 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.

CAROL SAYS GOODBYE

March 24 was the last day at the PAAB for Carol Johnston, the PAAB Submission Coordinator since 1991. She has retired and will spend her time in the Muskoka region. Actually, Carol had come to the PAAB in 1990 to fill in for someone on maternity leave. When a full time opportunity arose, we asked her to join the PAAB staff. Carol was a cornerstone of the PAAB staff and we appreciated her dedication, efficiency and loyalty. Carol had a way to know what was important and what was fair while dealing with clients. The PAAB staff will miss her.

PAAB MEETINGS

April 22, 2005 - Annual/General Meeting

June 10, 2005 - Executive Committee

November 17, 2005 - General Meeting

CODE REVISION

On December 3, 2004 the PAAB approved revisions to the PAAB Code of Advertising Acceptance. **Implementation of the new revisions will be April 1, 2005.**

The draft was written based on the results of a e-survey that was sent to PAAB board members, pharmaceutical companies, agencies, federal and provincial governments, healthcare associations, patient advocacy associations, medical publishers, CME providers, e-business suppliers and interested individuals. Over 70 written responses were received and analyzed by the Code Review Committee.

Two task forces were created to review two outstanding issues. One task force will look at the format and content requirements in the Code for prescribing information and fair balance. The other task force will look at the PAAB Code scope particularly with respect to nonprescription drugs and natural healthcare products. The Code is available on the PAAB web-site ww.paab.ca.

PROMOTION VS SAFETY INFO

Our goal is to provide advice on when healthcare product companies should send their material to the PAAB for review or whether they should consult Health Canada directly. If you believe that your company has to send a message about product safety

LOOK INSIDE

to either health professionals or the general public, you should send the letter, print message or broadcast message to Health Canada. They will assist you in putting out a clear and meaningful safety message. All other product-focussed messages would be promotional in nature and they should be sent to the PAAB for review.

We have seen examples of companies distributing promotional messages that they called safety messages, and they consulted neither Health Canada nor the PAAB. I consider that to be deceptive and unethical. Health Canada intervened in a prescription product promotional campaign in a national newspaper and the PAAB could have prevented that intervention had we been given the chance to review that advertisement. The result is more distrust of that company and the pharmaceutical industry as a whole. One company argued that they didn't have time to wait for the PAAB review. Companies shouldn't be in such a hurry to break the law. In fact, we have expedited reviews of messages that we believed were in the best interest of the target audience to get them sooner rather than later.

PAAB TRAINING INITIATIVE 2005

The PAAB is partnering with Pharmahorizons to continue a training project regarding the PAAB Code of Advertising Acceptance. The goal is to teach the application of the PAAB Code primarily to new pharmaceutical industry employees. Pharma-horizons will provide pro-fessional logistical support while the PAAB staff will provide and maintain control of all content. We will be adding content regarding the April 1 revisions to the PAAB Code. The next offering of this workshop will be in Toronto June 7 and in Montreal June 9. You can contact Pharmahorizons (1-888-514-5858) for information about future workshops.

GET DTCARX ADVICE

We remind you that PAAB will give an advisory opinion on specific projects that involve advertising or infor-mation directed at the general public. Currently, com-panies 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.

PRESCRIBING INFORMATION

Every once in a while bad practices creep back into the market place. We have noticed examples of companies highlighting or emphasizing specific aspects of the prescribing information in journals or in custom made product monographs. PAAB Code section 7.2.2 states "Underlining or other methods of emphasis that are not part of the product monograph are not acceptable". Section 7.2.1 allows shading, screening or coloring as long as it does not reduce legibility. Please comply with the PAAB Code of Advertising Acceptance.

CHANGE OF IMS POLICY

IMS Canada has announced a change in their policy regarding prior written consent to use IMS data to support claims in advertising. Effective June 1, 2005 any company wanting to have a promotional claim using IMS data will submit the claim and required accompanying information directly to the PAAB and no longer to IMS. IMS has agreed to provide training for and work with the PAAB review staff during a transition period. IMS is updating their publication guidelines to address any potential for ambiguity. The PAAB will be creating supplemental guidelines to help advertisers understand what is needed to support market share claims with respect to the PAAB Code of Advertising Acceptance.

REVIEW ACTIVITY

During the period of January 1to March 31, 2005, the total number of first review submissions reviewed was 983. This compared to 858 during the same period of 2004, a 14.6% increase.

During the first quarter of 2005, 64% of the submissions were given a first review response in five days or less compared to 22% in 2004 and 100% were given a first review response in 10 days or less.

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 complai-nant 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: January 1 to March 31, 2005

During the period of January 1 to March 31, 2004, the PAAB Commissioner processed 5 **Stage 2 complaints.** One complaint involved an APS with current approval by the PAAB and the complaint was rejected. The other 4 that did not have PAAB approval were sustained. PAAB reviewed 983 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 5 notices of violation in the fourth quarter. Four cases were sent directly to Health Canada because they involved allegations regarding Direct-to-Consumer drug advertising (3) and unapproved labeling (1).

STAGE TWO DECISIONS

1.
ADVERTISER: AstraZeneca
COMPLAINANT: Pfizer
SUBJECT: c04-60 Crestor (rosuvastatin) Promotional Letter to Physicians in November 2004
PRECLEARANCE: No

ALLEGATIONS: "Pfizer Canada remains firmly of the view that both the Crestor Safety Notice (which was in fact media ads) and the DDL (signed by … rather than the appropriate medical person at AstraZeneca) contain information which is inaccurate, false and misleading, and inappropriate information referencing CRESTOR and other statins and for all these reasons would not have been approved if AstraZeneca had submitted each of these materials for approval." AstraZeneca contends that the "Crestor Safety Notice" in newspapers was not advertising and that the letter to physicians about the newspaper article was not advertising subject to the PAAB Code of Advertising Acceptance.

PAAB DECISION: Pfizer had notified Health Canada of their complaint and the PAAB was informed that Health Canada considered the "Crestor Safety Notice" to be advertising by the regulations. Therefore the Commissioner ruled that the letter to physicians to notify them about Crestor advertising should have been sent to the PAAB for review with respect to Code s6.2.

PENALTY: Cease and desist further distribution and notification of the violation to Rx&D regarding penalty assessment in the Rx&D Code of Conduct.

OUTCOME: AstraZeneca agreed to cease distribution of the advertisement and letter. Health Canada had correspondence with AstraZeneca on the Direct-to-Consumer advertisement.

2.
ADVERTISER: Novo Nordisk
COMPLAINANT: Wyeth
SUBJECT: c04-63 Vagifem (estradiol) tip-in, 4-page leave behind and a branded counseling piece
PRECLEARANCE: No

ALLEGATIONS: APS had not been approved by the PAAB prior to distribution to health professionals

(Code s1 and s6). Misleading and Derogatory illustration comparing to Premarin Vaginal Cream and incomplete dosing information.

PAAB DECISION: Violation of PAAB Code regarding need to review and other allegations deferred to the PAAB review if Novo Nordisk agrees to submit the material to the PAAB for review.

PENALTY: Cease and desist distribution and possible destruction pending PAAB review.

OUTCOME: Novo Nordisk agrees to cease and desist distribution of all Vagifem promotional material and agrees to submit them for PAAB review and approval prior to further distribution.

3.
ADVERTISER: Hoffmann-LaRoche
COMPLAINANT: Schering
SUBJECT: Pegasys RBV (peginterferon alfa-2a)
PRECLEARANCE: Yes (DAF49281 August 2004)

ALLEGATIONS: Advertising is misleading because Roche "misrepresents and arificially inflates the sustained viral response (SVR) observed in cirrhotic patients with peginterferon alfa-2A plus ribavirin (S2.3.1 and 4.3.2). Schering also states "The APS makes unsubstantiated and misleading claims to SVR rates in cirrhotic patients of 52% (Hadzyannis et al) and 43% (Fried et al). The referenced publications clearly indicate that these response rates were observed in patients with bridging fibrosis or cirrhosis not solely in cirrhotic patients as the APS claims. PAAB Code 2.3.1, 4.3.2."

PAAB DECISION: A major consideration for any PAAB review is whether or not the claims are consistent the Health Canada authorized product monograph and the current clinical literature used to support the claims. We note that on page 45 of the PEGASYS RBV terms of market authorization (TMA, product monograph) there is a statement "The SVR for patients with cirrhosis was 50% (N=58/115)" and the statement is based on the Hadzyannis study data. On page 43 of the same TMA we see "The SVR for patients with cirrhosis treated with PEGASYS 180 mcg and COPEGUS 1000 mg or 1200 mg for 8 weeks was 41% (n=23/56 …". Therefore, it appears that the reprint authors and Health Canada do not share the same view as Schering on the use of this terminology. In addition, in their correspondence dated February 17, 2005, Roche has provided some information regarding the relevance of the specific classification to which Schering refers. Complaint is rejected.

PENALTY: $500 registration fee assessed to Schering.

4.
ADVERTISER: Berlex
COMPLAINANT: Organon
SUBJECT: Yasmin (estradiol/drospirenone) single sponsor newsletter "Contemporary Contraception: A Review of OC Options, Drospirenone: A distinct New Option" Volume 1 Number 1.
PRECLEARANCE: No

ALLEGATIONS: This promotional piece for Yasmin requires PAAB review and it is potentially misleading because it does not mention the bold warning seen in the Yasmin product monograph and emphasis is put on a weight loss claim that does not appear in the TMA. Berlex contends that the piece was not meant for distribution to health professionals.

PAAB DECISION: Agree with complainant that the piece is promotional and would require PAAB review.

PENALTY: Because of the large number that was distributed to physicians and not retrieved it was decided that a correction letter to include the missing information should be distributed by Berlex to the physicians that received the newsletter.

OUTCOME: Berlex agreed to issue a correction letter to the original audience that received the newsletter.

CONTACT INFORMATION

For information or if you have comments:

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