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.

PAAB MEETINGS / EVENTS

October 18, 2005 - Executive Committee

October 25, 2005 - Open Workshop in Toronto

October 27, 2005 - Open Workshop in Montreal

November 25, 2005 - General Meeting

Please note the PAAB office will be closed from December 26 to December 30 inclusive.

PAAB REVIEW EXEMPTIONS

Section 6.6 of the PAAB Code of Advertising Acceptance lists types of material that are exempt from PAAB review. This includes 6.6(a) "Information materials that have been independently controlled and prepared, with industry involvement limited to purchase and /or sponsorship of the distribution (example: a textbook)". The definition of advertising or promotion that is subject to the PAAB Code section 11.1 is "any paid message communicated by Canadian media with the intent to influence the choice, opinion or behaviour of those addressed by commercial messages. Distribution of any unsolicited material about a pharmaceutical product is deemed to be advertising if the information or its distribution serves to promote the sale of that product either directly or indirectly. This definition applies even if the information:

- has been published independently of the manufacturer
- is from an independent authoritative source
- is unchanged and complete
- is claimed to be educational material

Therefore, meeting reports that are commissioned by a sponsor about a subject that shows emphasis on the sponsor's product(s)and are distributed to an audience broader than the original meeting attendees would be deemed to be advertising subject to review by the PAAB. Please focus your attention on section 6.6.(a) of the PAAB Code rather than the definition of "independent publisher " in section 11.12. Distribution of complete accredited CME programs may not be advertising if the subject matter is not focussed on the sponsor's products. When in doubt, call the PAAB office.

VOLUME AND TURNAROUND

So far in 2005 the PAAB has received another record number of submissions to review. This is the fourth year in a row for an increase. The PAAB has a commitment to advertising sponsors to send a response on first review in ten working days or less. To date the PAAB has returned a first review in ten days or less 91% of the time. You can help us improve that record by: submitting complete submissions the first time in; not calling repeatedly to check on the status of your files; sending well-organized submissions more than 20 pages by courier, not by fax or e-mail. You can call the reviewers for clarification of letters they have written. You can request a meeting at the PAAB office to discuss concepts or launches. We charge a fee for that service.

MARKET SHARE CLAIMS

The PAAB has created supplemental guidelines to help advertisers understand what is needed to support market share claims with respect to the PAAB Code of Advertising Acceptance. The transition has been fairly smooth and we thank the sponsors for their cooperation. The guidelines are in effect and can be found in the "Supplemental Guidelines" section of the PAAB web-site www.paab.ca.

LOOK INSIDE

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 and provide a refresher for experienced personnel. Pharma-horizons will provide pro-fessional logistical support while the PAAB staff will provide and maintain control of all content. The next offering of this workshop will be in Toronto October 25 and in Montreal October 27, 2005. You can contact Pharmahorizons (1-888-514-5858) for registration and information about future workshops.

GET DTCARX ADVICE

We remind you that the PAAB will give an advisory opinion on specific projects that involve advertising or information directed at the general public. Currently, companies cannot advertise treatments of Schedule A diseases to the general public or advertise prescription drugs except for name, price, and quantity. We can assist you in interpreting Health Canada guidelines on what is advertising and what is not considered to be advertising. The 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. Health Canada has endorsed both the PAAB and Advertising Standards Canada to perform the review service based on the Health Canada guidelines. Advertisers are not required to send a particular submission to both the PAAB and ASC.

REVIEW ACTIVITY

During the period of July 1 to September 30, 2005, the total number of first review submissions reviewed was 1197. This compared to 987 during the same period of 2004, a 30% increase. For the year the number of first reviews was 3183 compared to 2802 during the first 9 months of 2004, a 13.6% increase.

During the first three quarters of 2005, 29% of the submissions were given a first review response in five days or less compared to 31% in 2004 and 92% were given a first review response in 10 days or less this year compared to 91% in 2004.

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: July 1 to September 30, 2005

During the period of July 1 to September 30, 2005, the PAAB Commissioner processed 8 Stage 2 complaints. Four complaints involved an APS with current approval by the PAAB and four complaints were rejected. Of the other 4 that did not have PAAB approval 3 were sustained and one rejected. PAAB reviewed 1197 advertising pieces during the same period. The total number of stage two complaints received during 2005 is 20. PAAB reviewed 3183 APS during the first six months of 2005.

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 1 notice of violation in the second quarter.

STAGE TWO DECISIONS

1. ADVERTISER: Lundbeck

COMPLAINANT: Pfizer

SUBJECT: #c05-29 Ebixa (memantine) Detail Aid

PRECLEARANCE: Yes #DAF51707 in January 2005

ALLEGATIONS: The claim "Ebixa … the first and only treatment for moderate to severe Alzheimer's disease" was not valid because other agents have been approved by Health Canada to treat moderate Alzheimers disease.

PAAB DECISION: Rejected the allegations because a check of the product monographs for the competitors' products revealed that the statement was valid. The claim was speaking to the range of patients covered by the approval and no other product shared that range at that time.

PENALTY: Pfizer was assessed the $500 registration fee.

OUTCOME: No further action required.

2. ADVERTISER: Axcan

COMPLAINANT: Procter & Gamble

SUBJECT: c05-30 Salofalk (5-ASA) Journal Ad

PRECLEARANCE: Yes as JAC52475 in March 2005.

ALLEGATIONS: The claim "Salofalk Oral is priced 35% less than Asacol at maximum daily dosing for the treatment of ulcerative colitis" implied therapeutic equivalence and the dosing and indications for Asacol were different.

PAAB DECISION: Rejected. The two products have a similar treatment of ulcerative colitis indication and the correct dose for that indication is shown. The price comparison through the minimum/maximum range is shown fairly, a proper disclaimer for the comparative clinical significance appears and the word "price" and "price per tablet" is clearly stated.

PENALTY: P&G was assessed the $500 registration fee.

OUTCOME: No further action required.

3. ADVERTISER: Novartis

COMPLAINANT: Hoffmann LaRoche

SUBJECT: c05-31 Myfortic (mycophenolic acid delayed release tablet) Detail Aid

PRECLEARANCE: No

ALLEGATIONS: The APS should have been sent to the PAAB for preclearance review (s1) because it was distributed in a promotional manner by sales representatives at an exhibit booth. The APS does not present a balanced profile of CellCept. By focussing only on an increased risk of acute rejection during periods of reduced dosing with CellCept and ignoring rigorous comparative studies showing a similar incidence of dose reductions with Myfortic, this APS is an unfair attack on CellCept that does not promote credibility and trust (s2.1). The retrospective cohort studies cited in this APS do not accurately represent the side effect profiles of CellCept (and Myfortic) as presented in the currently approved Myfortic product monograph supported by two comparative randomized trials that did not appear in the subject APS. (s3.2, 2.3). By focussing only on dose reductions with CellCept and failing to report similar outcomes with Myfortic, Novartis is presenting these data out of context and unfairly representing the adverse event profile of CellCept (s5.12, 5.14). Since this document is clearly an APS for Myfortic (further supported by their use of the Myfortic brand colours

PAAB DECISION: Sustained. Despite the logo of the University of Alberta appearing on the cover and the inclusion of a statement that this was an "interactive scientific program reviewed and approved by the Division of Continuing Medical Education at the University of Alberta", the manner of distribution was promotional in nature and intended to promote the sale of Myfortic. We agreed with the Roche allegations that the APS did not meet the requirements of several sections of the PAAB Code of Advertising Acceptance.

PENALTY: Cease unsolicited distribution. Rx&D was notified of the PAAB Code violation.

OUTCOME: Novartis agreed to cease distribution.

4. ADVERTISER: L'Oréal Canada

COMPLAINANT: Schering Canada

SUBJECT: c05-34 Ombrelle journal ad in "The Pharmacy Post" May 30, 2005

PRECLEARANCE: No

ALLEGATIONS: No preclearance review by the PAAB (s6.1). Specific claims were challeneged by Schering and PAAB had no comment because the appropriate reference material was not provided. L'Oréal Canada had agreed in stage one to cease distribution of the ad and to submit future advertising to the PAAB. The claims would be ruled on during the submission review process.

PAAB DECISION: Sustained. PAAB appreciates the commitment from L'Oréal Canada to send future advertising material for preclearance.

PENALTY: The distribution of the material was ceased. No further penalty was needed.

OUTCOME: L'Oréal Canada agreed to submit future advertising to the PAAB.

5. ADVERTISER: Valeant

COMPLAINANT: Québec Ministry of Health
Conseil du médicament

SUBJECT: C05-36 Cesamet (nabilone) Detail Aid

PRECLEARANCE: No

ALLEGATIONS: Off label promotion of Cesamet for chronic neuropathic pain.

PAAB DECISION: Sustained. We agrees with the Quebec ministry that there was overt off-label promotion. After review of the material it was noted that other elements of the detail aid had been rejected by the PAAB.

PENALTY: We sent the material and complaint to Health Canada with respect to the Health Canada policy regarding companies that were non-compliant with PAAB rulings.

OUTCOME: Still waiting for feedback from Health Canada on disposition of the complaint.

6. ADVERTISER:TEVA Neuroscience

COMPLAINANT: Biogen idec

SUBJECT: c05-39 Copaxone (glatiramer acetate) Detail Aid

PRECLEARANCE: Yes as DAF49164 in May 2004 and the subject claims were accepted previously in 2003.

ALLEGATIONS: inaccurate and incomplete data that lacks context in the claims "35% reduction at 9 months (0.50 (n=113) vs. 0.77 (n=115) placebo, mean, p=0.0077)" and "75% reduction at 2 years (0.60 (n=25) vs. 2.40 (n=25) placebo, mean, p=0.005)

PAAB DECISION: Rejected allegation that this presentation was consistent with the Copaxone Product Monograph as approved by Health Canada and was not overtly false or misleading. Agreed that in future presentations a range of effectiveness data may be more meaningful than just the product monograph data.

PENALTY: None.

OUTCOME: APS clearance has expired.

7. ADVERTISER: Boehringer Ingelheim

COMPLAINANT: Novartis

SUBJECT: c05-38 Micardis (telmisartan) journal ad

PRECLEARANCE: Yes as JAC52168 in April 2005

ALLEGATIONS: The graphic elements used in the Micardis ad were plagiarized from previously published Diovan series of ads (s2.1, 2.7).

PAAB DECISION: Rejected. The two ads use a vascularized human being as a graphic element. The colours, texture and extent of the vasculature are quite different. The context of the claims is different. Although there are some similarities, no substantive evidence of plagiarism was presented.

PENALTY: $500 registration fee assessed to Novartis

OUTCOME: No further action required.

8. ADVERTISER: Schering

COMPLAINANT: Hoffmann LaRoche

SUBJECT: C05-40 Meeting Report published by Pulsus as "From Protein to Patient Proceedings from a scientific symposium conducted at the 1st Annual CASL Winter Meeting Sunday March 20, 2005"

PRECLEARANCE: No

ALLEGATIONS: Item was an APS subject to PAAB review because it is promotional in nature and did not meet the exemption requirements in Code s6.6.a

PAAB DECISION: Sustained. The report was initiated in January 2005 and distributed after the April 1 Code revision. Roche alleged that the meeting was not accredited and was organized and sponsored by Schering. The meeting included a Schering employee as speaker. There were no specific allegations in the stage two letter that the report was false or misleading.

PENALTY: Cease distribution.

OUTCOME: Schering agreed to cease distribution of the report and to amend their SOP to include meeting reports and include the SOP as a component of company training. Roche contacted the PAAB Commissioner to indicate that they believed that some of the content was false and/or misleading and they had neglected to include that in the stage two letter although they had mentioned specific issues to Schering during the stage one process.

CONTACT INFORMATION

For information or if you have comments:

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