PHARMACEUTICAL ADVERTISING ADVISORY BOARD

# 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 21, 2005 – Executive Committee

October 25, 2005 – Open Workshop in Toronto

October 27, 2005 – Open Workshop in Montreal

November 25, 2005 – General Meeting

## 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

## LOOK INSIDE

matter is not focussed on the sponsor's products. When in doubt, call the PAAB office.

## 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. We have done this because IMS has changed their policy with respect to their validation of market share claims. The guidelines are a written version of what previously existed in principle and were applied to advertising. Hence, these are not new principles. The PAAB consulted the PAAB member organizations, clients who were frequent users of market share claims in their advertising and major suppliers of market share data used to support claims. The guidelines are in effect and can be found in the "Supplemental Guidelines" section of the PAAB web-site www.paab.ca.

## 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. Pharmahorizons will provide professional 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 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 April 1 to June 30, 2005, the total number of first review submissions reviewed was 995. This compared to 1026 during the same period of 2004, a 3% decrease. For the year the number of first reviews was 1985 compared to 1884 during the first six months of 2004, a 5% increase.

During the first half of 2005, 40% of the submissions were given a first review response in five days or less compared to 34% in 2004 and 99.2% were given a first review response in 10 days or less this year compared to 85% 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 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: April 1 to June 30, 2005

During the period of April 1 to June 30, 2005, the PAAB Commissioner processed 7 **Stage 2 complaints**. Five complaints involved an APS with current approval by the PAAB and four complaints were rejected. The other 2 that did not have PAAB approval were sustained. PAAB reviewed x advertising pieces during the same period. The total number of stage two complaints received during 2005 is 12. PAAB reviewed 1985 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 3 notices of violation in the second quarter.

## STAGE TWO DECISIONS

1.

**ADVERTISER**: Pfizer

**COMPLAINANT:** Merck Frosst

**SUBJECT**: c05-06 Relpax Dose Card approved as DAF50813 in October 2004, Journal ad approved as JAF50377 in October 2004

**PRECLEARANCE:** Yes

**ALLEGATIONS**: Dose Card: a)Tagline "Powerful initial option for migraine patients" is not supported by the product monograph and clinical guidelines because Relpax is recommended for moderate to severe migraine, not all forms of migraine.

b) Relpax clinical study results vs. sumatriptan: The p-value refers to statistical significance, and the percentages in isolation without an absolute number of patients is misleading. It suggests that the outcome was that much better, not that *a certain % more patients* achieved the same outcome."

c) We are questioning the use of checkmarks as bullets in front of the medications listed. The visual of the checkmark suggests that those medications can be taken without risk of adverse events. The statement that adverse event frequency remains unchanged, without stating if the frequency is high or low, does not mitigate the impression presented by the visual. There is a specific warning in the product monograph about appropriate observation of a patient taking Relpax and SSRI's concomitantly, and yet SSRI's appear on the list with a checkmark next to them.

Journal Ad: "…to her migraine success". We maintain that a pharmaceutical company creating

their own definition of a word (in this case, the word "success") is not appropriate.

**PAAB DECISION**: Dose Card: a) It appears that both sides agree that current medical opinion directs the use of triptans as first-line therapy for moderate to severe migraines. This is not clearly stated in the dose card.

b) I agree with Pfizer that the results are presented accurately and appropriately and there is no violation of Code section 4.3.

c) I agree with Merck Frosst that the precaution about concomitant use with SSRIs should be included to qualify the implication that there is nothing to worry about. Code section 2.4 requires inclusion of the safety statement to balance the controlled trial results that are not sufficient to guarantee that no reaction could happen.

Journal Ad: I do not agree with the Merck Frosst interpretation that the headline does not meet the requirements of the PAAB Code. The statement re "success" is supported by the fact that Relpax has been deemed to be safe and effective for the treatment of migraine headache. Other corrections as noted in the Dose Card should be made.

**PENALTY:** Cease distribution of materials immediately.

**OUTCOME:** Pfizer agreed to stop distribution and to revise all materials with the subject content that was ruled as violative.

2.

**ADVERTISER**: Hoffmann LaRoche

**COMPLAINANT:** Eli Lilly

**SUBJECT**: c05- 08 Nutropin Compassionate Use Application Form and Letter

**PRECLEARANCE:** No

**ALLEGATIONS**: Letter and form are promotional in nature and should be precleared by the PAAB. Also, the letter included an indication that was not approved in Canada (s3.1).

**PAAB DECISION**: Agreed with Eli Lilly of the two violations of the PAAB Code. In stage one Roche stated that the form was a pickup from U.S. material, hence the indication error.

**PENALTY:** In stage one, Roche had admitted to the error of the indication and had agreed to send the material to the PAAB for review and to inform their representatives to retrieve existing material from the marketplace.

**OUTCOME:** Roche complied with the PAAB decision.

3.

**ADVERTISER**: GlaxoSmithKline

**COMPLAINANT:** Private Physician

**SUBJECT**: c05-10 Advair Detail Aid reviewed by the PAAB as DAF50049 and accepted in September 2004.

**PRECLEARANCE:** Yes

**ALLEGATIONS**: Dosage of Advair should be clearly stated in product promotion related to the GOAL study.

**PAAB DECISION**: Agreed with complainant "In order for the GOAL results to be appropriately applied in real life, any advertising documents related to this study must clearly state the dose of medication, including duration of use, associated with the primary outcomes presented in such documents (s2.1).

**PENALTY:** PAAB clearance withdrawn**.** Cease distribution of this APS. It was noted that GSK had applied the principle of this ruling to other APS and this APS was an exception.

**OUTCOME:** GSK complied with the decision.

4.

**ADVERTISER**: Biogen idec

**COMPLAINANT:** Serono

**SUBJECT**: c05-11 Amevive Patient Information APS

**PRECLEARANCE:** No

**ALLEGATIONS**: Patient Information distributed via health professionals. APS should be reviewed by the PAAB (s6.4) and should not include comparative promotional claims of efficacy and safety.

**PAAB DECISION**: Violation of the PAAB Code.

**PENALTY:** Cease distribution. In stage one correspondence prior to the Serono stage two request, Biogen idec stated they believed they were compliant with the PAAB Code and they were willing to dialogue further with Serono.

**OUTCOME:** Biogen complied with the ruling and would submit the document for PAAB review prior to further distribution.

5.

**ADVERTISER**: Pfizer

**COMPLAINANT:** Lundbeck

**SUBJECT**: c05-13 Aricept dose card

**PRECLEARANCE:** Yes, accepted as DAC46395 in October 2003.

**ALLEGATIONS**: Data claims about moderately-severe Alzheimer's disease is not consistent with the product monograph indication.

**PAAB DECISION**: Reject complaint. The data that appears in the APS is consistent in content with what appears in the Terms of Market Authorization (Product Monograph) that was approved by Health Canada for Aricept.

**PENALTY:** No further action required of Pfizer. Lundbeck was assessed a $500 registration fee.

6.

**ADVERTISER**: Axcan Pharma

**COMPLAINANT:** Ferring

**SUBJECT**: c05-18 Salofalk Patient Information APS distributed with SmartSamples. Materials in package include physician benefits, patient benefits, advertising and pricing copy, "Did You Know?" backing sheet, "Did You Know? IBD" brochure.

**PRECLEARANCE:** Partially - brochure approved by the PAAB in October 2004 as SVE50354.

**ALLEGATIONS**: Axcan has mixed the editorial piece on Irritable Bowel Disease with Salofalk branded pieces in one package resulting in Direct-to Consumer promotion and off label indication promotion.

**PAAB DECISION**: The PAAB approved the editorial piece as a stand alone consumer information brochure. It is not acceptable within the current law to mix branded and unbranded elements in the same package to consumers resulting in the promotion of an unapproved indication.

**PENALTY:** Axcan to cease distribution, inform the sales representatives to cease distribution until package complies with the PAAB Code (2.1, 3.1).

**OUTCOME:** Axcan agreed to comply with the PAAB ruling.

7.

**ADVERTISER**: Berlex

**COMPLAINANT:** Wyeth

**SUBJECT**: c05-26 Yasmin Detail aid approved by the PAAB as DAF51547 in February 2005.

**PRECLEARANCE:** Yes

**ALLEGATIONS**: Claim of "Yasmin is the #1 dispensed branded OC in North America" is misleading because it is not #1 in Canada.

**PAAB DECISION**: Agreed that while the claim is factual, it is potentially misleading because market share claims should be relevant to the Canadian market place. This principle was confirmed by recent PAAB consultation of stakeholders.

**PENALTY:** Cease distribution and revise current material.

**OUTCOME:** Berlex complied with the decision.

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**CONTACT INFORMATION**

**For information or if you have comments:**

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