PHARMACEUTICAL ADVERTISING ADVISORY BOARD JANUARY 20

PAAB REVIEW

Year 2007 marks the 31st 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

February 9, 2007 – Executive Committee Meeting

April 11, 2007 – Revised Code Workshop, Toronto

April 12, 2007 – Revised Code Workshop, Montreal

April 20, 2007 – Annual/General Meeting

CODE REVISION

On November 24, 2006 the PAAB approved revisions to the PAAB Code of Advertising Acceptance. **Implementation of the new revisions will be July 1, 2007.** It is anticipated that advertisers will want to make adjustments to their advertising plans ahead of that date and the PAAB will approve advertising that reflects the changes for July implementation. It is generally agreed that promotion will influence prescribing habits and thus you will note that the bar is high for the standard of evidence used to support claims in advertising, exceeding the standards required for CME presentations. Stakeholder feedback will be solicited after implementation of the new Code requirements.

The current code will be in effect until July 1, 2007. Approved advertising may run until expiration date although complaint decisions about advertising in the marketplace after July 1 will be based on the revised code. So please adjust your advertising schedules to comply with the new code.

Key Change Elements Include:

1. Harmonization with Health Canada terminology throughout the Code.
2. Section 2.4 and explanatory notes Fair Balance requirements – a modest change designed to redistribute minor information and study parameters from the body copy with a shift to the Prescribing Summary Box (s7.3). Major safety information and necessary qualifying information (e.g. dosing adjustments in certain patient populations or indication limitations) are still required to be shown. The goal is to redistribute the mass of small-type footnotes on the main display area of the advertising. The reviewers will work with advertisers to adjust to the new code requirement. The end result in each ad will be dependant on the product monograph.
3. Section 2.8 - The requirement for a specific contact person from the sponsor's Medical or Regulatory or Compliance departments to sign off on the advertising prior to sending it to the PAAB. it is the sponsor's corporate responsibility to designate an accountable person. We are "eliminating" the possibility for agencies to send materials to the PAAB at the same time as the sponsor. We want to review market ready material from the

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sponsor's viewpoint. The PAAB does not review and approve marketing objectives. The PAAB review is a scientific/ clinical/ regulatory review and therefore we want to know that qualified people from the sponsor agree with the material we are reviewing.

4. Sections 3.2.2 and 3.2.3 – revised wording to strengthen the message that statements should be consistent with the Terms of Market Authorization and no literature supporting off label claims will be acceptable.
5. Section 5.10.1 – some claims may be supported by peer reviewed, published meta-analysis. Use caution in interpreting this section because not all meta-analyses are of high enough quality to be accepted as support for advertising. The PAAB will reject sub-standard studies.
6. Section 5.11 Disclosure of Study parameters – it will be acceptable to put certain study parameters in the Prescribing Summary Box. The reviewers can help you during the review process.
7. Sections 5.13 and 5.14 – new wording regarding equivalence claims and formulation studies
8. Section 6.1 – a requirement for the use of a new icon in journal ads to link to the indexed Prescribing Information. These icons will be available for download from the PAAB web-site.
9. Section 6.6. exemptions from PAAB review for some small ads. Note other requirements of the PAAB Code and Food & Drugs Act may apply e.g. the need for prescribing information.
10. Section 7 – a major shift including extensive changes in the Prescribing Information format and content requirements. Larger type requirement for "Prescribing Summary Box" information. Deletion of Full and Condensed Disclosure and replacement by requirements for "Advertising With Product Claim Prescribing Information". This resulted from research with doctors performed by CAMP and the PAAB. Health Canada was consulted early and late in the revision process. The approved format was rated high by physicians in readability and usefulness to clinical practice.
11. Section 11 Definitions – a few changes there.

The Code is available on the PAAB web-site www.paab.ca. Booklets and CDs will be available for purchase from the PAAB office.

PAAB CAN HELP YOU

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-focused 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 link to a pharma company sponsor and the appearance that it is promoting the sale of the sponsor's product(s).

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**.

COMMUNICATION PROJECT

The PAAB has engaged Healthworld and Hill and Knowlton to conduct an advertising and public relations campaign directed at physicians to create more awareness of the value-added service that the PAAB provides to pharmaceutical advertisers. The goal is to help physicians become aware of the PAAB and appreciate pharmaceutical advertising that bears the PAAB logo. The recent prescribing information requirements will be a focus of the campaign message.

Advertisements telling doctors about the PAAB preclearance review service will appear in selected Canadian medical journals during 2007. Also, the PAAB is seeking the help of publishers to carry articles about the PAAB and the Code of Advertising Acceptance. Call Commissioner Chepesiuk to tell us about your opportunity to help the PAAB.

If you see components of the campaign, please share your opinion with the PAAB Commissioner at commish@paab.ca.

PAAB TRAINING INITIATIVE 2007

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 professional logistical support while the PAAB staff will provide and maintain control of all content. We will be presenting content regarding the July 1, 2007 revisions to the PAAB Code. The next offering of this workshop will be in Toronto on April 11 and in Montreal April 12. You can contact Pharmahorizons (1-888-514-5858) for information about the workshops.

GET DTCARX REVIEW 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.

UNPRECEDENTED REVIEW ACTIVITY

The commissioner commends the PAAB office staff for their dedication and exemplary work during the sixth consecutive record volume year. During the period of October 1 to December 31, 2006, the total number of first review submissions reviewed was 1,410. This compared to 1,262 during the same period of 2005, a 12% increase. From January 1 to December 31, 2006 there were 5,281 first reviews compared to 4452 during the same period in 2005, a 18.6 % increase. To handle the record workload, the PAAB added 2 reviewers and 1 admin staff in 2006.

During the fourth quarter of 2006, 30% of the submissions were given a first review response in five days or less and 100% were given a first review response in 10 days or less. During 2006 19% of first reviews were completed in five days or less, 70% in ten days or less and 11% have exceeded ten working days.

COMPLAINTS / MONITORING

PAAB COMPLAINT REPORT

Period: October1 to December 31, 2006

During the period of October 1 to December 31, 2006, the PAAB Commissioner processed 3 **Stage 2 complaints**. PAAB reviewed 1,410 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 advertiser's trade association and/or Health Canada for their assessment of additional penalties. PAAB sent 1 notice of violation in the fourth quarter.

STAGE TWO DECISIONS

Update on Complaint c06-22 Boehringer Ingelheim Aggrenox (dipyridamole –ASA) promotion. Boehringer Ingelheim agreed to waive the stage 3 appeal by panel ruling if the commissioner was successful in getting a Health Canada ruling on the complaint. Health Canada agreed and ruled that the activity was in violation of the Food & Drugs Act because it was an off-label promotion. Boehringer

Ingelheim agreed with the ruling and took appropriate action as requested by the PAAB. Rx&D was notified of the PAAB Code violation. Please note that there was an error in the original account in the October PAAB Review. Solvay was not a complainant and it should have read Sanofi-Synthelabo. We apologize to Solvay for any confusion that listing may have caused.

1.

ADVERTISER: Wyeth

COMPLAINANT: Janssen-Ortho

SUBJECT: c06-29 Wyeth Editorial APS "A Guide to Contraception and Management of Side Effects"

PRECLEARANCE: Yes, as DAE56310 in March 2006

ALLEGATIONS: "JOI requests that it be clearly and prominently identified on the chart that hormonal activity differs among various oral contraceptives and that physicians cannot compare products with different hormones on a milligram to milligram basis." (s2.1 and s4.1)

PAAB DECISION: The chart presentation appears to be consistent with the presentation in the Dickey reference. Therefore, it is factual. There is a disclaimer on the page "Comparative clinical significance has not been abolished". See s4 "Total Hormone Content" in Supplementary PAAB Guideline for Oral Contraceptive Advertising.

PENALTY: $500 registration fee assessed to Janssen-Ortho.

OUTCOME: Case dismissed.

2.

ADVERTISER: Biovail Canada

COMPLAINANT: Lundbeck Canada

SUBJECT: c06-33 Wellbutrin XL (bupropion) Exhibit Booth Panels shown at Canadian Psychiatric Association conference

PRECLEARANCE: No

ALLEGATIONS: Item was not precleared by the PAAB (s1 and s6.3). Claims of comparability of and graphical efficacy representation of Wellbutrin XL (bupropion) and Celexa (escitalopram). It is a pooled analysis (s3.1) and the dosage of Wellbutrin is higher than the approved maximum and the dosage of escitalopram is much lower than the approved maximum. (s5.3).

PAAB DECISION: Item appears to be misleading based on the PAAB Code and Health Canada guidelines for therapeutic comparisons. This is a second time offence for similar activity. Health Canada was informed.

PENALTY: At time of publication, awaiting Biovail response to the decision.

OUTCOME: Health Canada notified of repeat violation of PAAB Code and alleged violation of Food and Drugs Act.

3.

ADVERTISER: Novartis

COMPLAINANT: Oryx Pharmaceuticals

SUBJECT: c06-35 Prexige (lumiracoxib) advertising in October 17, 2006 *Medical Post* "Understanding the TARGET Trial, CV Outcomes First in a Series of Four"

PRECLEARANCE: No

ALLEGATIONS: PreNOC advertising

PAAB DECISION: Send complaint to Health Canada as per HC policy

PENALTY: At discretion of Health Canada and Rx&D.

OUTCOME: Decision by Health Canada that the Medical Post series of articles was "advertising" subject to the regulations and the PAAB Code and the promotion was pre-NOC in violation of the Food & Drugs Act. The commissioner sent a notification of the decision to Rx&D.

CONTACT INFORMATION

For information or if you have comments:

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