PHARMACEUTICAL ADVERTISING ADVISORY BOARD

April 2009

PAAB REVIEW

Year 2009 marks the 33rd 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.

PLEASE NOTE THAT THIS NEWSLETTER IS ONLY AVAILABLE ON THE PAAB WEB-SITE AS OF JANUARY 1, 2009

PAAB MEETINGS

April 17, 2009 - Annual General Meeting

April 30, 2009 – Training Workshop Toronto

VACCINE DTCA ADVISORY

We remind you that when distributing Direct-to-Consumer vaccine advertising with claims including television broadcast advertising to consumers, they must comply with Food & Drugs Act section 9.1. For the past number of years, the PAAB has asked clients to add fair balance risk information in a manner similar to the requirement in section 2.4 of the PAAB Code of Advertising Acceptance. Despite being on Schedule D of the FDA, vaccines are considered to be similar to prescription-requiring drugs. The PAAB recommends that advertising should include cautionary statements and inclusion of safety information in vaccine advertisements directed to consumers.

Health product advertisements that omit important facts and fail to present fair and balanced representations of the benefits and risks of a health product may create an erroneous impression and therefore may be considered misleading and thereby not in compliance with section 9(1) of the FDA. In the case of direct-to consumer advertising of vaccines, the communication of safety information such as the unknown duration of immunity, potential contraindications in certain populations, potential side effects or allergic reactions, potential need for booster doses, the limited protective role, etc. could be deemed appropriate measures to provide more balanced information to consumers.

DIRECT-TO-CONSUMER RX

The PAAB allows advertisers to include the PAAB logo on DTC material reviewed by the PAAB and that reach a "no further comment" stage. Prescription-requiring drug ads including drugs, biologics and vaccines directed to consumer television require a Telecaster number available from the Television Bureau of Canada. Telecaster will accept a letter from the PAAB as proof of valid review prior to authorizing a number. The PAAB is the only agency with a 32 year history of reviewing prescription drug advertising.

Written opinions regarding Direct-to-Consumer Advertising of Prescription Drugs and opinions regarding whether an activity is advertising subject to the PAAB Code will be given to the client within 4 business days. Please use the PAAB eFile submission system available at www.paab.ca and clearly indicate your request for an opinion. If you have any questions please call Glenn Golaz or Patrick Massad at the PAAB office 905-509-2275.

Look Inside

PAAB reviews include branded ads, help-seeking ads, web-sites and consumer brochures on all media. Reviews are based on the Health Canada document "The Distinction between Advertising and Other Activities". PAAB will charge a review fee for written opinions, including e-mail (see Fee schedule on web-site). Advertisers should note that the PAAB members have agreed to the Health Canada request that it be copied on final versions of DTCARx material reviewed by the PAAB.

CODE REVISIONS APRIL 1, 2009

At the PAAB General Meeting of November 20, 2008, the PAAB Members approved the following revisions to the Explanatory Notes section of the PAAB Code of Advertising Acceptance. *These revisions came into effect on April 1, 2009.*

Section 2.4.3

With respect to advertising of nonprescription drugs and natural health products, the fair balance requirement can be met by inserting the following statements into the APS.

For products with a Product Monograph: "See Prescribing Summary on page XX for information to assist in benefit-risk assessment. Always direct the patient to read the label."

For products without a Product Monograph: "See Warnings, Cautions and Directions of Use on page XX for information to assist in benefit-risk assessment. Always direct the patient to read the label." (Note: also see s7.2.1).

Section 3.1.7

With respect to advertising of nonprescription drugs without a Product Monograph, a Senior Regulatory official of the Market Authorization Holder (MAH) may provide an attestation to PAAB to confirm that a claim has been approved by Health Canada. "Name of the Market Authorization Holder hereby attests that the claim (specific expanded claim) has been authorized by Health Canada for (complete product Brand name)." The MAH may be asked to provide further information.

Editorial Note: The change to code s3.1.7 would affect only non-prescription DIN products. It would not affect NHP products. The rationale was that, for non-prescription DIN products, "no reply" from Health Canada for minor changes to the TMA may be taken as acceptance. This lack of paper trail does not occur in the NHP category and PAAB reviewers should ask for the product license claims approved by Health Canada.

Section 6.4.3

Company controlled or prepared branded patient information is information that contains non-promotional material that is consistent with, and in addition to, the consumer information section of the product monograph. The information should focus on educating patients about particular diseases/conditions and optimal use of the product by the patient for whom it has been prescribed.

This information should address patients' expectations through encouraging meaningful dialogue between patient and healthcare professional and supplementing this dialogue with the best available evidence-based statements.

All health product information must be consistent with the Terms of Market Authorization, and should not contain promotional claims.

The Advertising/Promotional System (APS) could contain additional sources of health information from standard setting organizations. It should be written in clear, understandable and legible language.

Principles for education on optimal use of the product and diseases/conditions:

Principle 1: Clarity of message
Principle 2: Manage expectations
Principle 3: Evidence-based information
Principle 4: Un-biased sources of information

CUSTOMER EXPERIENCE INDEX

The PAAB's primary role is to ensure that advertising of prescription drugs is accurate, balanced and evidence based. The PAAB staff strives to provide service that is accurate, transparent and prompt, demonstrating a high level of scientific and regulatory expertise in its reviews.

In late May, 2008, we introduced a Customer Experience Index Survey (CEI). This will provide the PAAB with a systematic and ongoing tool for client feedback, measuring administration, reviewers, management, general process and technology.

Clients who have had an APS accepted will be randomly selected to receive a survey involving 14 questions. If you get one, please complete it and send it back to us promptly. It is important to answer the questions regarding the referenced review file. It is the commitment of the PAAB to improve our customer service.

PAAB CLIENT TRAINING

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. Pharmahorizons will provide professional logistical support while the PAAB staff will provide and maintain control of all content. **The next session will be in April 2009.** You can contact Pharmahorizons (1-888-514-5858) for information about the workshops and registration.

REVIEW ACTIVITY

During the period of January 1 to March 31, 2009, the total number of first review submissions was 1,182. This compared to 1,208 during the same period of 2008. During the first quarter of 2009, 100% of submissions were given a first review response in 10 days or less, the same as during the same period of 2008.

PAAB COMPLAINT REPORT

Period: January 1 to March 31 2009

During the period of January 1 to March 31, 2009, the PAAB Commissioner processed 4 Stage 2 complaints. PAAB reviewed advertising pieces during the same period. One complaint about a previously reviewed file was upheld in one of the four allegations.

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.

STAGE TWO DECISIONS

1. ADVERTISER: Servier

COMPLAINANT: Abbott

SUBJECT: c09-01 Coversyl (perindopril) Detail Aid

PRECLEARANCE: No

ALLEGATIONS: At least one Sales Representative was distributing material that was not reviewed by the PAAB. The subject of the material included comparative claims that would not meet the requirements of section 5 of the PAAB Code. Servier claimed that the material was for internal use only.

DECISION: Agree with complainant.

PENALTY: Servier to cease and desist distribution, recall the material, and send an action plan of what measures they will take to prevent such a violation in the future. Rx&D notified of the violation.

OUTCOME: Servier complied with the PAAB ruling. The action plan was comprehensive and included an invitation for a PAAB code learning workshop.

2. ADVERTISER: Servier

COMPLAINANT: Abbott

SUBJECT: c09-02 Coversyl (perindopril)

PRECLEARANCE: No.

ALLEGATIONS: Laminated 2-sided card exhibit booth material at the 12th Annual Cardiac Conference November 5, 2008 with unsubstantiated comparative claims of safety and efficacy (s5.7.1, s2.4). Allegation that material was previously rejected by the PAAB.

DECISION: Servier to cease and desist distribution, recall the material, and send an action plan of what measures they will take to prevent such a violation in the future. Rx&D notified of the violation.

PENALTY: Servier to cease and desist distribution, recall the material, and send an action plan of what measures they will take to prevent such a violation in the future. Rx&D notified of the violation.

OUTCOME: Servier complied with the PAAB ruling. The action plan was comprehensive and included an invitation for a PAAB code learning workshop.

3. ADVERTISER: Ambrillia

COMPLAINANT: Novartis

SUBJECT: c09-03 Web-site and Press Release promotion of an investigational drug. PAAB copied on letter to Health Canada.

PRECLEARANCE: No

ALLEGATIONS: Pre-NOC promotion of a drug with comparative claims

DECISION: Due to Health Canada policy on pre-NOC drugs, Health Canada will adjudicate the complaint.

PENALTY: Unknown.

OUTCOME: Unknown.

4. ADVERTISER: Lundbeck

COMPLAINANT: Boehringer Ingelheim

SUBJECT: c09-04 Cipralex (escitalopram) detail aid and journal ad

PRECLEARANCE: Yes (October 2008 and February 2009)

ALLEGATIONS: Four allegations:

1. Tagline "Because depression and GAD are at work every day" implies an indirect therapeutic claim that Cipralex helps people get back to work (s3.1.1). Only the journal ad was accompanied by a pictorial office setting.

2. The claim "Powerful Efficacy" is absolute with no statistical information as a qualifier (s4.2.1)

3. Comparable efficacy data presentations fail to show any statistical significance (s5.9)

4. The subheading "Excellent Tolerability Profile" does not reflect an attitude of caution with respect to drug usage (s2.4) and the calim is not accompanied by the necessary fair balance 9s2.4.1)

DECISION: 1. Agreed only in the case of the journal ad that the combination of the tagline and pictorial presented an unsubstantiated claim.

2. Rejected the allegation re claim "Powerful Efficacy" has been accepted by the PAAB ad infinitum based on the product monograph indication.

3. Rejected the allegation re data presentations met the requirements of the PAAB code section 5.9.

4. Rejected the allegation re The claim "Excellent Tolerability Profile" was supported by the product monograph and it included the necessary fair balance qualifying information usually required by the PAAB.

PENALTY: Due to minor nature of violation and good cooperation of Lundbeck, no further penalty was deemed necessary. Revise journal ad to change either the pictorial graphic or the tagline. No action required on rejected allegations.

OUTCOME: Lundbeck agreed to comply with the PAAB decision.

For information or if you have comments:

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