PHARMACEUTICAL ADVERTISING ADVISORY BOARD

October 2009

# PAAB REVIEW

Year 2009 marks the 33rd year of the PAAB since its incorporation in 1976. To see the current edition of the PAAB Code, visit the PAAB Web-site.

**www.paab.ca**

Ce document est également disponible en français sur notre site web.

## PAAB MEETINGS

November 9, 2009 – Social Media Marketing Workshop Toronto

November 27, 2009 - General Meeting

## MISSION, VISION, VALUES

**MISSION**: To provide a preclearance review that fosters trustworthy healthcare communications within the regulatory framework.

**VISION**: Trusted healthcare product communication that promotes optimal health.

**VALUES**: Integrity, Competency, Credibility, Independence, Excellence, Transparency

## SOCIAL MEDIA MARKETING

Due to requests from our clients, the PAAB conducted a training workshop on Social Media Marketing "What Works in Canada" on September 29, 2009 in Montreal and September 30 in Toronto. They were successful and due to demand the PAAB will be conducting another session in Toronto on November 9, 2009. We have assembled a panel of experts from Industry, Health Canada and the PAAB to interact with our clients to learn best practices in Canada. Pharmahorizons is providing logistics support. It will be a full morning session. Mark your calendars for November 9, 2009 in Toronto only. You can get more info from the PAAB web-site and we will be sending an e-mail blast to clients.

## PRODUCT INFORMATION (PI) COMMITTEE

The PAAB Directors have struck a code committee of various industry stakeholders to review how product information (PI) is delivered to the target audience in various media. The committee surveyed Rx&Dclients to measure the understanding of and the impact of the PI code changes of 2007. The committee decided that more work needs to be done and the PI Committee will request funding from the PAAB for more extensive research involving direct interviews with senior marketing officials representing all PAAB clients. Options will be reviewed and a suggestion to the board is expected to follow. Any changes will have to be within the current federal regulatory framework and the opinion of Health Canada will be sought.

## RESEARCH COMMITTEE

As part of the strategic plan set in 2007, the PAAB directors have struck a research committee, chaired by Dr. Walter Rosser, to reward grants to researchers in Canadian pharmaceutical drug advertising. The committee is sending out requests for projects to selected researchers and hopes to award the first grants in the Fall of 2009.

## 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 provides a seamless

review of advertising campaigns that include health professionals, patients and consumers.

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.

PAAB reviews include branded ads, help-seeking ads, web-sites and consumer brochures on all media including television and internet. 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.

## 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. Results for the first six months of 20009 indicated an 80% satisfaction level with the individual file that the client commented on. The PAAB commissioner is pleased with the results and is encouraging the staff to keep up the good work.

## RX&D CLIENTS INVITATION

We remind you that the door to the commissioner's office is open to receive comments about PAAB staff performance. He would like to receive specific examples that caused dissatisfaction for the client to help identify trends for areas of improvement of the PAAB review service. Our Customer Experience surveys and personal cognizance have not revealed the comments raised by Rx&D staff at recent meetings with PAAB officials. We would like to document and investigate specific cases and report back to Rx&D about action taken. You can contact the commissioner at 905-509-2275 x28 and by email at commish@paab.ca.

## REVIEW ACTIVITY

During the period of July 1 to October 31, 2009, the total number of first review submissions was 1,200. This compared to 1,119 during the same period of 2008. Year to date 2009, 99% of 3,717 submissions were given a first review response in 10 days or less compared to 100% of 3,547 in 2008.

## PAAB COMPLAINT REPORT

### Period: July 1 to September 30 2009

During the period of July 1 to September 30, 2009, the PAAB Commissioner processed 5 Stage 2 complaints. PAAB reviewed 1,200 advertising pieces during the same period. The total number of stage two complaints for 2009 is 10.

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: MERZ

COMPLAINANT: Allergan

SUBJECT: Xeomin (clostridium botulinum neurotoxin type A(150kD) , free from complexing protein) APS, booth display and mailer

PRECLEARANCE: No

ALLEGATIONS:

1. Horse Chestnut Visual Analogy – the visual presents a misleading message.

2. "Free from Complexing Proteins" when combined with Horse Chestnut Visual. – Implies clinical comparative advantage not supported by clinical evidence.

3. "Low Potential for Neutralizing Antibody Formation" – the claim implies clinical significance where there is none and is not in the product monograph.

DECISION:

Allegation #1. - The choice of this visual implies that Xeomin is emerging as something more desirable from an outer layer that is different and possibly less desirable. Advertising visuals are carefully selected by the sponsor to convey a message. What is the message? The visual message by itself is not entirely clear. When taken with the wording "free of complexing proteins", a feature that is seen in the Terms of Market Authorization approved by Health Canada, we can interpret that the message is that Xeomin has left the complexing proteins behind. However, the long term clinical significance of this statement has not been proven and the product monograph shows limited data. A disclaimer about the unknown long term clinical effects would be required. If one knows the market place, the context of the visual with the statement "Low potential for neutralizing antibody formation" implies that Xeomin is more desirable because competitors have complexing proteins that create a higher potential for neutralizing antibody formation" as a result of their formulation. That has not been proven and the statement "Low potential for neutralizing antibody formation" is not included in the Terms of Market Authorization. While we have no objection to the horse chestnut visual on its own with the term "Free of Complexing Proteins" with a disclaimer "Long term clinical significance not known", in the context of the two APS in question the combination of the visual and statement "low potential …" is not accepted.

Allegation #2 - The literature and Xeomin product monograph show that there is no proven clinical advantage shown by the fact that Xeomin is "Free from Complexing Proteins" at this point in time. As stated in allegation #1, the visual and statement without the disclaimer "long term clinical significance unknown"in combination with the statement "low potential …" is potentially misleading 2.1, 3.1.1.

Allegation #3 - This claim is not in the Health Canada approved Product Monograph and there does not appear to be sufficient evidence to support the claim. We agree with Allergan that there is a violation of code section 2.3 and 3.1.

Important Additional Violation of PAAB Code s2.4. - We note that there is a black box copy and a bold warning in the Xeomin product monograph and other relevant safety or risk information that should be provided in the ad copy. The indication is not clearly stated in a prominent manner. No provision of fair balance safety information is a violation of PAAB Code section 2.4 and may provide a safety hazard for doctors prescribing this new product. This is alleged to be a violation of the Food and Drugs Act s9(1). The indication should be accurate and stated prominently in future advertising. It does not appear to be adequate in this APS.
PENALTY: Merz chose not to use the PAAB advertising preclearance review mechanism to help them produce accurate, complete and clear advertising. While we do not agree exclusively with the Allergan argument, we do agree with Allergan that there are several violations of the PAAB Code of Advertising Acceptance as outlined

previously. Merz should discontinue use of this potentially misleading advertising (exhibition booth and mailer) immediately. Merz should send a written action plan to the PAAB commissioner within 5 working days from July 14, 2009 as to how they will comply with this ruling. Based on the Health Canada policy with respect to their working relationship with the PAAB, we will send the complaint with my safety allegation to Health Canada for further investigation and possible regulatory action if Merz chooses not to comply with the PAAB ruling. Please see the HC policy **PAAB and Health Canada Roles and Consultation Related to Advertising Review** at http://www.hc-sc.gc.ca/dhp-mps/advert-publicit/pol/role_paab-ccpp-eng.php.

OUTCOME: Merz complied with the ruling. Health Canada was informed of the alleged potential patient safety issue.

**2.** ADVERTISER: Shire

COMPLAINANT: Procter & Gamble

SUBJECT: several Mezavant (Mesalamine) APS

PRECLEARANCE: Yes

ALLEGATIONS: A comparative data presentation adapted from the Product Monograph was potentially misleading because it was included in the product monograph for safety/tolerability assessments, and not for efficacy related measures. P&G questioned the encapsulation of Asacol for the trial and whether appropriate testing was done to prove equal bioavailability. Code sections 5.7 and 5.14 were cited.

DECISION: Specific APS were not provided by P&G making it difficult to assess the context of the use of data comparison. It is common practice that pharmaceutical companies select data and statements from a product monograph to be put into advertising messages. The PAAB position is "if it is in the TMA (product monograph) it can be used in advertising". We know that this is consistent with Health Canada (HC) policy. This situation does not appear to be unusual. Also, we are aware that HC encourages comparisons to market standard drugs during the new drug approval process. We agree with Shire that they are showing the data presentation in a manner consistent with the data presentation in the product monograph. They have included the appropriate disclaimers seen in the product monograph and accepted by Health Canada.. This complies with sections 3.1 and section 4 of the PAAB Code of Advertising Acceptance. The encapsulation issue is moot because we believe Health Canada would have considered that factor when deciding on the validity of the data. We do not agree with P&G that selective presentation of these data is done in a misleading manner. Health professionals would be able to understand the message based on what is presented. A thorough review would include the context of the presentation and as stated earlier, that was not provided by P&G. We remind both companies that the PAAB considers context when reviewing statements or data pulled from product monographs. Rejected.

OUTCOME: During post-decision discussions with P&G, specific details were cited and the PAAB agreed to apply some review adjustments to future Mezavant APS. Shire has agreed to those adjustments.

**3.** ADVERTISER: Novo Nordisk

COMPLAINANT: Sanofi-Aventis

SUBJECT: Levemir (insulin) APS purported to be a newsletter to SOLVE clinical trial investigators

PRECLEARANCE: No

ALLEGATIONS: A sidebar in the newsletter titled "Newly Published" included selected efficacy information about a different trial using Levemir and appeared to be promotional in nature and therefore bound by advertising requirements in PAAB Code s2, 4, 5.6 and 5.11. "The message was sent to healthcare professionals, the message was entirely controlled by Novo Nordisk and the message contained a prominently displayed claim for a drug".

DECISION: Agreed with Sanofi-Aventis that the activity constituted advertising with respect the Health Canada document "The Distinction Between Advertising and Other Activities" and the PAAB Code applied. The item did not meet the exemption criteria in the Health Canada policy document "The Distinction Between Advertising and Other Activities" and there were several violations of PAAB Code sections 2, 3, 5 and 7 occurred. Novo Nordisk could have prevented this occurrence by sending the complete clinical paper in an appropriate manner to health professionals.

PENALTY:

1. Novo Nordisk should cease and desist from distributing this particular letter in the future.
2. Novo Nordisk should review its standard operating procedure regarding dissemination of material to clinical investigators contracted by the company to avoid future breaches of the regulations.
3. Novo- Nordisk should train its employees on the proper dissemination of investigational messages to clinical investigators and other health professionals.
4. Novo Nordisk should send an action plan as to how it will carry out the above three requirements, to the PAAB no later than August 13, 2009. Failure to do so would require further action by the PAAB Commissioner to notify Health Canada of the perceived breach of the Food & Drugs Act and Regulations.

OUTCOME: While Novo Nordisk agreed to stop further distribution of the newsletter, they did not agree with the PAAB that the activity constituted "advertising" subject to the PAAB code. The commissioner sent a request to Health Canada to investigate the complaint.

**4.** ADVERTISER: Boehringer Ingelheim

COMPLAINANT: AstraZeneca

SUBJECT: Micardis (telmisartan) "Get On Target" patient information program

PRECLEARANCE: Yes

ALLEGATIONS: "The overt connection between the title of this program and off-label information related to Micardis, together with its promotional nature, place the program in violation of the PAAB Code namely … s3.2.3, 6.4.3". There is a "Free Offer" of a blood pressure monitor.

DECISION: Although clever, we do not believe there is a direct connection from the ONTARGET study to the "Get on Target" patient program. We appreciate the intent of the AstraZeneca allegation re PAAB Code s3.2.3 with reference to off-label promotion. That is an important function for the PAAB to guide companies away from off-label promotion during the submission review process. AstraZeneca states that 82% of physicians knew about the OnTarget study as of May 2009. We warn all companies that Health Canada could step in if they perceived a pre-NOC advertising campaign and we are not aware that that has happened with the Boehringer Ingelheim perceived heavy pre-NOC ONTARGETtrial promotion.

1. it is common terminology in hypertension and other diseases or conditions to get people on target and the PAAB has approved multiple advertising campaigns with the subject of "target" involved.
2. we note that the "ONTARGET" trial has a distinct spelling and style that is different than that used in the "Get On Target" patient program.
3. we note that there is no mention of the actual ONTARGET study in the related promotional pieces that are subject of the study.

Rejected.

PENALTY: $500 registration fee assessed to AstraZeneca.

OUTCOME: No appeal.

**5.** ADVERTISER: MERZ

COMPLAINANT: Allergan

SUBJECT: APS Meeting Invitation for Xeomin (clostridium botulinum neurotoxin type A (150 kD, free from complexing proteins)

PRECLEARANCE: No

ALLEGATIONS:

I. "The Biggest Breakthrough in Botulinum Type A in Over a Decade" violates s2.1, 2.3, 3.1, 5.16 of the PAAB Code.

II. "The Purity Axiom" is potentially misleading because there is no clarity in its meaning and is unsubstantiated.

III. Missing Prescribing Information s7.3.

IV. Other alleged violations.

DECISION:

I "The Biggest Breakthrough in Botulinum Type A in Over a Decade"

Sections 2.1, 2.3, 3.1, 5.16 apply to this claim. We have not seen evidence to support such a claim.

II "The Purity Axiom"

Sections 2.1, 5.16, 3.7 apply to this claim. There is no clear explanation of what this means and we are not aware of any proven clinical significance related to this terminology. This is a promotional claim without meaning and looks like Merz is claiming special status.

III "Prescribing Information" aka Product Information

Section 7.3 applies. This is a major omission.

IV Other Alleged "Violations"

In the opinion of the PAAB, this meeting invitation is a promotional vehicle subject to the provisions of the PAAB Code of Advertising Acceptance and the Food & Drugs Act and Regulations. We note that there is a black box copy and a bold warning in the Xeomin product monograph and other relevant safety or risk information that should be provided in the ad copy. The indication is not clearly stated in a prominent manner. No provision of fair balance safety information is a violation of PAAB Code section 2.4 and may provide a safety hazard for doctors prescribing this new product. This is alleged to be a violation of the Food and Drugs Act s9(1). The indication should be accurate and stated prominently in future advertising. It does not appear to be adequate in this APS.

PENALTY: There are violations of the PAAB Code in this APS. Merz should send a written action plan to the PAAB commissioner by October 9, 2009 as to how they will comply with this ruling. Based on the Health Canada policy with respect to their working relationship with the PAAB, we will send the complaint with my safety allegation to Health Canada for further investigation and possible regulatory action if Merz chooses not to comply with the PAAB ruling. Please see the HC policy **PAAB and Health Canada Roles and Consultation Related to Advertising Review** at http://www.hc-sc.gc.ca/dhp-mps/advert-publicit/pol/role_paab-ccpp-eng.php.

We encourage Merz to submit future advertising to the PAAB to help them comply with the PAAB Code of Advertising Acceptance. Please call us if you need help with the process. The PAAB helps companies stay out of the complaint track. If you choose not to correct these APS and future APS, we will request enforcement action from Health Canada by registering a complaint.

OUTCOME: Waiting MERZ response at time of publication.

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

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