PAAB REVIEW

Year 2006 marks the 30th 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

April 21, 2006 - Annual/General Board Meeting

May 16, 2006 - Open Workshop in Toronto

May 18, 2006 - Open Workshop in Montreal

July 6, 2006 - Executive Committee Meeting

30 YEARS!

By Ray Chepesiuk

Wow! PAAB is celebrating 30 years since it was incorporated in 1976. This may not be as exciting news to most of you who haven't been in this industry all that long and have only known the PAAB as part of the drug advertising regulation scene. When I came to the PAAB I had the privilege of being trained by the very first commissioner, Arnold Raison. I heard the stories of the beginning of the PAAB and I appreciate the fact that it was a lot harder to work at the PAAB at a time when it was a mystery to most folks why it even existed. I was delighted to receive an e-mail message from Arnold's daughter congratulating the PAAB on growing to what it is today. A good seed was planted 30 years ago.

PAAB TRAINING INITIATIVE 2006

The PAAB will continue its training project regarding the PAAB Code of Advertising Acceptance with the assistance of Pharmahorizons. 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 May 16 and in Montreal May 18, 2006. You can contact Pharmahorizons (1-888-514-5858) for registration and information about future workshops.

PAAB CODE SECTION REVISION

Effective January 1, 2006 the following paragraph has been added to section 6.6.a of the PAAB Code of Advertising Acceptance. It replaced a similarly worded paragraph. "Meeting Reports of sections of accredited Health Professional Meetings or Continuing Education (CE) events/activities (see s 11.10) organized independently of the sponsor of the materials and that are not focused on, or provide emphasis on, the sponsor's product(s) i.e. do not promote the sale of the sponsor's product(s)." Also sections 11.11 and 11.12 definitions have been removed. You can see the Code at www.paab.ca.

The initiative to make the change came from the Canadian Association of Medical publishers. That was the impetus for this recommendation as well as the Commissioner having experienced many comments about potential confusion in the application of these code sections. The current wording reflects the Health Canada interpretation of advertising with respect to meeting reports. You can see that in the Health Canada guideline "The Distinction Between Advertising and Other Activities" available on the Health Canada web-site.

LOOK INSIDE

HELP US HELP YOU

From time to time the PAAB staff members ask me to communicate some issues to our clients. Please take note of the following:

1. Please ensure that you have Medical/Regulatory approval for your advertising project before it gets submitted to the PAAB for review. Concurrent review is not acceptable. The Commissioner may have to take action against certain submitters for abusing code requirement 8.1.d.

2. Organize yourself better and please ensure we have the final version for our review. It is time wasting to send in a revised version before we send a letter to the client asking for revisions.

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 January 1 to March 31, 2006, the total number of first review submissions reviewed was 1279. This compared to 992 during the same period of 2005, a 29% increase.

During the first quarter of 2006, 21% of the submissions were given a first review response in five days or less compared to 64% in 2005; and 79% were given a first review response in 10 days or less this year compared to 36% in 2005. Detail material comprised 37% of the volume followed by service oriented material (including patient information) at 23%.

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: January 1 to March 31, 2006

During the period of October 1 to December 31, 2005, the PAAB Commissioner processed 8 Stage 2 complaints. Five complaints involved an APS with current approval by the PAAB and four of the complaints were rejected. The other three complaints that did not have PAAB approval were sustained. PAAB reviewed 1279 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 advertisers trade association and/or Health Canada for their assessment of additional penalties. PAAB sent 1 notice of violation in the first quarter, Health Canada was notified of the potential violations of the Food & Drugs Act regarding a public newspaper ad.

STAGE TWO DECISIONS

1. ADVERTISER: GlaxoSmithKline

COMPLAINANT: AstraZeneca

SUBJECT: c05-58 Advair (salmeterol xinafoate & fluticasone propionate) Journal Ad in Medical Post November 1, 2005

PRECLEARANCE: Yes July 2005

ALLEGATIONS:
1. Claims of "No Asthma symptoms" and "Total Control" are false and misleading.
2. Claim for 44% of patients achieving total control would have to indicate "low-dose corticosteroid users" and "mild-to moderate asthmatics".
3. Stratum 3 results should be disclosed.
4. The "Asthma Control" logo should not be used in this context.

PAAB DECISION: 1. This appears to be a similar complaint as c05-10. The headline is well-qualified by "as a possibilityfor many patients as shown in the GOAL study" and all of the necessary parameters are stated in the advertisement.

The patient population achieving this result is stated in the footnote and is not misleading and does not require immediate change. GSK and the PAAB can work on improving the clarity of this claim in future advertising.

3. This advertisement could be improved by adding the stratum 3 results. The dosage does seem to be within the Advair product monograph. I do not believe that this APS needs immediate revision.

4. We agree with GSK that the Asthma Control logo has been used appropriately in Advair advertising since 2000 and that the Total Control phrase is well-qualified in the ad. Putting the Total Control term in quotations should be considered for future advertising because it is a technique that has been suggested by the PAAB in the past to other advertisers and may provide distinction that this is a qualified claim.
This APS does not require immediate revision.
The ad does not need immediate revision.

PENALTY: $500 registration fee assessed to AstraZeneca.

OUTCOME: No appeal.

2. ADVERTISER: Biogen idec

COMPLAINANT: Serono

SUBJECT: Amevive (alefacept) journal ad

PRECLEARANCE: Yes October 29, 2004

ALLEGATIONS:
1. The term "sustained efficacy" is absolute and guarantees sustained efficacy to all Amevive patients when this is not the case based on the clinical data.

2. Statement "Treatment with Amevive 7.5 mg IV was associated with clinical response shown to last over 7 months (median 216 days) without flare-ups or disease rebound" needs to be balanced better to more accurately reflect the fact that only a minor subset of patients will achieve a sustained effect.

PAAB DECISION: A significant fact was raised by Serono in their correspondence. As of a product monograph change in May 2005, it appeared to Serono and to me that Amevive was no longer available in an I.V. formulation. Therefore claims based on the I.V. formulation appearing in advertising would be potentially misleading. Biogen Idec has provided a correct version of the PM that includes the I.V. formulation. This was a source of confusion. The Prescribing information approved in October 2005 as JAF55251 is incorrect because the PAAB review was based on the incorrect product monograph provided by Biogen Idec. The review of JAF49945 based on the original product monograph appears to have been consistent with that product monograph. I believe the "sustained efficacy" claim related to the support of I.V. data in the PM is acceptable. Also, if efficacy claims based on I.V. data appear in future APS, the data should be prominently disclosed right

beside the claim and in the same font and type size because the current advertising contains type size that should be larger and should not be in a remote footnote that is difficult to find.

The PAAB withdraws clearance of the prescribing information JAF55251 effective immediately.

PENALTY: I will make the PAAB staff aware of this decision and the PAAB can help expedite changes in the ad. The cost of immediately revising the prescribing information should be sufficient penalty for Biogen Idec for the confusion they have caused and they could have addressed this issue in Stage One.

OUTCOME: Biogen has informed me in writing that they will correct the prescribing information immediately and make future adjustments to the i.v. disclaimer as requested by the PAAB.

3. ADVERTISER: Eli Lilly

COMPLAINANT: Health Canada

SUBJECT: Actos (pioglitazone) Dear Doctor Letter and Reprint

PRECLEARANCE: No

ALLEGATIONS: Distribution of a Dear Doctor Letter and article that is related to a study on an off-label indication for Actos (pioglitazone). "While the manufacturer states that they cannot promote the use of a product outside of its approved indication and Product Monograph, it mentions that physicians always have the possibility to make a clinical judgment to use it off-label".

PAAB DECISION: Violation of PAAB Code sections 6.2 (preclearance requirement) and 3.1 (off-label).

PENALTY: Notification of violation of the PAAB Code to Rx&D and to Health Canada.

OUTCOME: Eli Lilly stated they had a misunderstanding of the rules for this type of communication. They agreed to cease this type of activity. Rx&D ruled a violation and assessed a fine.

4. ADVERTISER: Theramed

COMPLAINANT: Innovapharm

SUBJECT: c06-03 Delatestryl (testosterone enanthate) Brochure "Your Patients, Your Practice" distributed at a conference

PRECLEARANCE: No

ALLEGATIONS:
A. Promotional Publication "Your Patients, Your Practice" - It was distributed by sales representatives and not PAAB precleared (s6.3). Claims are not consistent with the HPFB accepted product monograph. (S3.1). Claim for use of testosterone enanthate for s.c. injection is based on an unpublished, small study, not peer-reviewed (s3.1.1). This sales aid poorly presents data in a way that was misleading and ambiguous. An unpublished cohort study of <20 patients was the source for this.

B. Dosing Card: Delatestryl
No PAAB logo (s6.3) and indication was not consistent with the product monograph (s3.1). Lacks Fair Balance (s2.4)

PAAB DECISION: During Stage One and after discussion with the PAAB Commissioner Theramed officials agreed to cease distribution of the materials alleged to be in violation, inform their sales force of that decision have their future APS reviewed by the PAAB. There was some misunderstanding during the stage one correspondence leading to a Stage Two registration. The Commissioner agreed with the complainant about the alleged violations of the PAAB Code. Theramed confirmed their cooperation with the PAAB.

PENALTY: Cease distribution of violative materials. The Commissioner did not agree with Innovapharm that a corrective letter would be appropriate in this case.

OUTCOME: Theramed agreed with the PAAB decision.

5. ADVERTISER: Pfizer

COMPLAINANT: Private Physician

SUBJECT: c06-04 Lipitor (atorvastatin) Journal Ad in New England Journal of Medicine January 2006

PRECLEARANCE: Yes approved November 2005

ALLEGATIONS: "There are no trial data to support the claim in the ad that a hypothetical 56 yr old hypertensive female smoker with type 2 diabetes or whose dad died early from CHD or has proteinuria [etc.] will have her risk of myocardial infarction reduced". "Lipitor has no all-cause mortality benefit trials to its name for either gender, or diabetics and now only treats "dyslipidemia". "Therefore, to not be misleading to prescribers and patients, the ad should state that Lipitor reduces cv 'events' ONLY in some male populations [defined by ASCOT] but that such 'event' reduction in males does not reduce overall mortality."

PAAB DECISION: The statements in the ad in question were consistent with the Health Canada approved indication and there was no emphasis through words or graphics for a claim regarding women. After discussion with the complainant, the Commissioner learned that the complainant believed the Health Canada approved indication was incorrect and should be changed for patient safety reasons. The PAAB referred the complaint to Health Canada for their investigation into the complainant's allegations.

OUTCOME: Health Canada agreed with the PAAB and the complaint was rejected.

6. ADVERTISER: Wyeth

COMPLAINANT: Berlex

SUBJECT: c06-06 Alesse (levonorgestrel - ethinyl estradiol) Comparison Card

PRECLEARANCE: Yes August 2005

ALLEGATIONS: "The advertisement is an unfair and misleading comparison of products with different medicinal ingredients and should be withdrawn immediately" and "is in violation of sections 5.10 (reliable data) and 5.14 (scare tactics) of the code." PAAB DECISION: Rejected. "The APS is directed to health professionals. I do not agree with Berlex that this information is presented in a manner that is misleading and that would scare doctors into prescribing Alesse. I agree with Wyeth that the comparison chart is presented in a manner that is consistent with the PAAB supplementary guideline "Estrogen-Progestin Combination Oral Contraceptives". While not mentioned in the complaint, I am bringing Wyeth's attention to the inclusion of the comparative promotional claims: "The #1 newly prescribed low-dose pill in Canada" and "Less makes sense". Those claims should not appear in the context of the estrogen-progestin chart. Wyeth should prepare future APS keeping that point in mind."

PENALTY: Assessed Berlex with $500 registration fee

OUTCOME: No Appeal. Berlex filed a second complaint based on the Commissioner's comments in this decision and Wyeth withdrew the APS from the marketplace.

7. ADVERTISER: GlaxoSmithKline

COMPLAINANT: AstraZeneca

SUBJECT: c06-08 Advair (salmeterol xinafoate & fluticasone propionate) "CONCEPT" mailer

PRECLEARANCE: Yes November 2005

ALLEGATIONS: Section 5.2 violation because the two drugs are not used at equivalent doses.

PAAB DECISION: Rejected. On page two of the Fitzgerald CONCEPT trial reprint we see "It was not a comparison of 2 drugs used at equipotent doses ... but of two treatment strategies using products appropriate for the population studied." The PAAB has approved material for AstraZeneca Symbicort that included claims of "flexible dosing". It seems rational to show a comparison of two drugs within the confines of their respective product monographs that are dosed in a different manner and AstraZeneca has done that in their promotional material. There was no intent to misrepresent

proper dosing for either drug and this appears to be a fair comparison. I do not see a violation of Code section 5.2.

PENALTY: $500 registration fee assessed to AstraZeneca.

OUTCOME: no appeal filed at time of going to print.

8. ADVERTISER: Genpharm

COMPLAINANT: Abbott

SUBJECT: c06-09 Euthyrox (levothyroxin) Journal Ad in Pharmacy Practice February 2006 and L'Actualité pharmaceutique January 2006

PRECLEARANCE: No

ALLEGATIONS:
1. Not precleared (s6.1).
2. The claim "Interchangeable with Synthroid in Quebec" is inaccurate and misleading. Health Canada has not declared Euthyrox to be interchangeable with Synthroid. And while Euthyrox does appear on "la modification No 11 Liste de médicaments du Québec d'octobre 2005," it has not been deemed interchangeable with Synthroid by Le Conseil du médicament" (s2.1)
3.The advertisement should have included balance copy (s2.1.2).
4.The advertisement should be accompanied by prescribing information (s6.1)

PAAB DECISION: The ad was not precleared and and did not include prescribing information or sufficient fair balance copy. At time of printing, the PAAB was waiting for Abbott to fulfill a request to provide documentation regarding allegation #2.

PENALTY: Pending

OUTCOME: Pending

CONTACT INFORMATION

For information or if you have comments:

Pharmaceutical Advertising Advisory Board
375 Kingston Road, Suite 200
Pickering, Ont. L1V 1A3
Tel: (905) 509-2275
fax: (905) 509-2486
e-mail: info@paab.ca
www.paab.ca