Pharmaceutical Advertising Advisory Board **October 2002**

PAAB UPDATE

PAAB
ACTIVITIES DURING THE
THIRD QUARTER OF 2002

Year 2002 marks the 26th year for 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

Several important meetings with respect to strategic planning will be happening in the next few months.

October 1 - Client Focus Group - Mississauga
October 2 - Staff Focus Group - Pickering
October 8 - Client Focus Group - Montreal
November 15 – Board Strategic Planning Meeting, 9 am to 5 p.m. at CFPC in Mississauga
December 12 – Executive Committee
January 17, 2003 – Annual/General Meeting

Educational Meeting Reports

Commissioner Chepesiuk is hearing that many "Education" reports that are being called exempt from PAAB review do not meet the requirements of sponsor independence and may not be objective and balanced. Some people may perceive this exemption as a loophole in the system that allows companies to promote off-label claims or to make unfair comparisons to competitors. This perception appears to be expanding. This is a reminder that **product-focussed** (i.e. emphasis on sponsor's drug products) messages distributed by the products' manufacturer may be deemed to be advertising subject to federal regulations, regardless of the fact that they meet the PAAB exemption from review guideline. The PAAB Commissioner suggests that companies respect federal law as well as the PAAB Code when they are considering sending reports with single product emphasis. Please note that an item may be exempt from PAAB review, yet may still be advertising. They may be subject to complaints under the PAAB Code and possible investigation by Health Canada vis a vis the Food & Drugs Act.
The PAAB guideline for exemption was based on the requirements in the Health Canada policy document "The Distinction Between Advertising and Other Activities". Objective and balanced means that the content does not have emphasis on the sponsor's product.
The PAAB guideline can be seen on our web-site www.paab.ca. Don't hesitate to call the PAAB Reviewers for advice and guidance.

Review Activity

During the period of July 1 to September 30, 2002, the total number of submissions reviewed was 802. This compared to 698 during the same period of 2001, a 15% increase.
In 2002, the total number of submissions reviewed year-to-date was 2380, an 17.5% increase compared to the 2001 total of 2025.

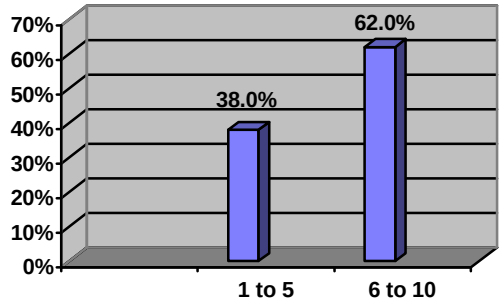
The proportion of advertising vehicles that were submitted for review shows 46% of the workload oriented towards detail aid activity.

LOOK INSIDE

Share of ads reviewed

During 2002, 38% of the submissions were given a first review response in five days or less and 100% were given a review response in 10 days or less.

Turnaround Time to First review



Direct To Consumer Advertising

This is a reminder that the PAAB provides an advisory opinion service on specific DTCRx initiatives. The opinion is given based on the interpretation of the Health Canada Policy document "The Distinction Between Advertising and Other Activities". A fee is charged for specific projects. We are also pleased to answer telephone calls for general advice on DTC regulations.

COMPLAINTS AND 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.

Code Section 9 contains a guide for the resolution of complaints about pharmaceutical advertising. Sponsors are encouraged to act in the spirit of the Code to seek resolution and abide by those terms, even in specific situations that are not directly anticipated in section 9.

There are three different 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; accept the advertiser's response; or 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 from individuals named by national organizations.*

PAAB COMPLAINT REPORT

Period: July 1, 2002 to September 30, 2002

During the period of July 1 to September 30, the PAAB Commissioner processed 7 **Stage 2 complaints**. This number brings the total for 2002 to 18. PAAB reviewed 2380 advertising pieces during the first nine months of 2002.

Of the 7 complaints, 6 were generated from advertising that had been previously PAAB-reviewed. Two of these complaints resulted in withdrawal of PAAB's previous acceptance. One complaint on advertising that was not PAAB-approved was sustained.

PAAB has continued to regularly **monitor** journals, the Internet, selected conferences and receive direct-mail/detail aid materials collected by health professionals as part of its monitoring program. During the second quarter of 2002, a total of 2 monitoring letters were issued. This brings the total for this year to 18. 1 case was referred to Health Canada because of perceived patient safety issues.

Commissioner's Note: Based on the content of the complaints we have seen, the pharma industry appears to be pressing the PAAB to be more restrictive in its submission file reviews.

STAGE TWO DECISIONS

1.

ADVERTISER: GlaxoSmithKline

COMPLAINANT: Novartis

SUBJECT: c02-13, 2 Valtrex (valcyclovir) Journal ads

PRECLEARANCE: Yes, in July 2001

ALLEGATIONS: Novartis alleged violations with respect to Code sections 3.1 and 3.2. Claim #1 – " … and it has been shown to shorten the duration of post-herpetic neuralgia (PHN)" – the statement appears to be consistent with data shown in the Valtrex product monograph (PM). Novartis was not aware that in 1996 after the introduction of Famvir, PAAB had sought a clarification of what PHN advertising claims were consistent with the Valtrex Product Monograph from Health Canada. The two monographs appeared to have different indication wording with respect to PHN. Health

Canada did not raise objections to the Valtrex advertising at that time and the PAAB strived to keep Valtrex advertising to be consistent with the Health Canada advisory. There have been no significant changes in the Valtrex PM since 1996 that would affect the Health Canada advisory. There did not appear to be undue emphasis on the PHN claim. Claim #2 – "Valtrex helps stop Zoster pain". The statement appears to be consistent with statements in the Valtrex product monograph.

PAAB DECISION: Both allegations rejected.

PENALTY: $500 registration fee assessed of Novartis.

OUTCOME: Remind GSK and PAAB Reviewers to respect the Health Canada advisory about the Valtrex product monograph in future APS.

2.

ADVERTISER: Abbott

COMPLAINANT: AstraZeneca

SUBJECT: c02-47 Prevacid (lansoprazole) detail aid

PRECLEARANCE: yes, in April 2002

ALLEGATIONS: The presentation of the headline of a study published in *Clinical Drug Investigation* as a headline in a promotional piece was misleading because the headline was not an accurate reflection of the study. See PAAB Code section 2.1 that states APS should not mislead and should promote credibility and trust. The headline was "Evidence for Therapeutic Equivalence of Prevacid 30 mg and Esomeprazole 40 mg in the Treatment of Erosive Oesophagitis". The study title was inappropriate because the study was not powered to demonstrate "equivalence". AstraZeneca stated "where differences in efficacy are accepted to be less than 10% (as expected in comparisons of PPIs) large sample sizes are required to determine any difference. The sample size for the cited paper was less than 300."

PAAB DECISION: Agree with AstraZeneca that the title of the paper was a claim for Prevacid that was not well supported by evidence and thus, potentially misleading. That would be a violation of PAAB Code section 2.1. No therapeutic equivalence was demonstrated nor could it be demonstrated by the study methodology. We question why a peer-reviewed publication would accept and publish such a title when it appears to be misleading and promotional in nature. The study methodology could be described as a "non-inferiority" study and does appear to be underpowered to detect any difference between the two agents. Any company should be cautious about how they use such a study for promotion.

PENALTY: Abbott to cease distribution of this detail aid immediately.

OUTCOME: Abbott sent a letter to all field representatives to cease distribution of this APS and to return unused materials to the head office. The PAAB Commissioner reminded PAAB Reviewers not to accept statements in advertising that were not supported by good evidence, irregardless of the verbatim accuracy to peer-reviewed published studies and irregardless of how hard the sponsor pushes for the statement. Medical-Regulatory departments who screen advertising should not accept such representations in advertising.

3.

ADVERTISER: Lundbeck

COMPLAINANT: Wyeth-Ayerst

SUBJECT: c02-43 Celexa (citalopram) dosage card that was part of a larger detail aid

PRECLEARANCE: yes, in September 2001

ALLEGATIONS: Wyeth-Ayerst alleges that use of a quote from the CANMAT guidelines for maintenance therapy for anti-depressant drugs implied a claim of full remission for Celexa and that was not in accordance with the Product Monograph. See Code section 3.1.

PAAB DECISION: The Dose Card headline on page one was "Select Celexa for convenient dosing". The statements on page two and three were related to specific dosing information and cautions from the product monograph. On page four the headline was "New 2001 CANMAT Guidelines for Maintenance therapy" and the copy was related to statements that pertained to all antidepressant agents regarding duration of use. There was no presentation of Celexa efficacy data related to full remission nor was there any emphasis on "full remission". Therefore, the complaint was rejected.

PENALTY: Wyeth-Ayerst was assessed a $500 registration fee.

OUTCOME: PAAB Reviewers were advised to be cautious about use of guidelines and class statements due to sensitivity level of advertisers.

4.

ADVERTISER: Janssen-Ortho

COMPLAINANT: Abbott

SUBJECT: c02-52 Pariet (rabeprazole sodium) Detail Aid

PRECLEARANCE: Yes, in June 2002

ALLEGATIONS: #1 – the statement "small enteric-coated once daily tablet taken with or without food day or night" was misleading because it was not complete because a 2 x 10 mg dosage was also promoted in the APS. Abbott contends that the full range of dosing alternatives should be presented

each time dosing is discussed" to be in accordance with Code section 2.1.2.
#2 – Abbott contends "that the pricing alternatives should be presented in full whenever the dosing and pricing options are presented with due prominence to avoid confusion …" with respect to Code section 2.1.2.

PAAB DECISION: #1& 2 – PAAB has received no evidence that physicians are confused by the APS and PAAB is aware that several provincial formularies have seen the Pariet APS and have expressed no dissatisfaction with them. The information related to dosing and pricing is complete within this APS thus the complaint is rejected.

PENALTY: Abbott is assessed a $500 registration fee.

OUTCOME: The PAAB Reviewers were advised of the increased sensitivity level of advertisers regarding dosing and pricing issues.

5.

ADVERTISER: Janssen-Ortho

COMPLAINANT: Abbott

SUBJECT: c02-55 Pariet (rabeprazole sodium) Detail Aid

PRECLEARANCE: Yes, in May 2002

ALLEGATIONS: #1 – Abbott states that the statement "the lowest priced PPI = patient savings" would not be true if a provincial formulary or a private payer paid for the prescription. "The patient will not realize any savings, only the payer will.". Also, three different prices for Pariet are shown in the APS and one of them is the same price as one other PPI.
#2 – the statement "price relief at a daily cost 40% less than omeprazole" may mislead one into thinking that this is always the case.
#3 – the inclusion of the single 10mg pill beside the price comparison with omeprazole followed in close proximity by the assertion "maintenance of healing of erosive or ulcerated GERD 10 mg as low as 65 cents a day" is bound to create confusion regarding which price is appropriate for each indication.

PAAB DECISION: PAAB has received no evidence that physicians are confused by the APS and PAAB is aware that several provincial formularies have seen the Pariet APS and have expressed no dissatisfaction with them. The formulary-approved 2x10 dosing and pricing is clearly explained. Use of a tablet as a "bullet" marker on all of the bulleted statements is not misleading because the information in the bullets is relevant and complete. The information related to dosing and pricing is complete within this APS thus the complaint is rejected.

PENALTY: Abbott is assessed a $500 registration fee.

OUTCOME: The PAAB Reviewers were advised of the increased sensitivity level of advertisers regarding dosing and pricing issues.

6.

ADVERTISER: AstraZeneca

COMPLAINANT: Merck Frosst

SUBJECT: C02-58 - Meeting Report "Late Breaking Medical News" brought to you by The Medicine Group Limited entitled "Atacand use protects the brain" in June 2002.

PRECLEARANCE: No.

ALLEGATIONS: The meeting report should have been PAAB reviewed as a promotional piece because it does meet all of the requirements of the PAAB Meeting Report guideline for exemption from review. Merck Frosst states that the following areas were violated "product references must be objective, balanced and scientifically rigorous", "… products will on most occasions be cited using non-proprietary (generic) names", when there is discussion of any use which is outside the limits of the Canadian monograph, this must be adequately disclosed", "the purpose of the report must be educational", and "it is not clear on the item that it was sponsored by AstraZeneca or that there was an agreement in place to ensure the independence of reporting".

PAAB DECISION: Agree with Merck Frosst that this item is focussed on the promotion of Atacand and should have been sent to the PAAB for preclearance. It does not meet the requirements of the PAAB Meeting Report Guideline for exemption from PAAB review. It also violates several other sections of the PAAB Code.

PENALTY: AstraZeneca to cease distribution immediately and to send a correction letter to the original target audience stating that the promotional item was sponsored by AstraZeneca and stating the Atacand indications approved by Health Canada.

OUTCOME: AstraZeneca agreed with the ruling and has sent a correction letter for PAAB review and approval. The PAAB is waiting for AstraZeneca to tell them that the letter has been distributed to the original target audience.

(Commissioner's Comment – see the page one article "Educational Meeting Reports")

7.

ADVERTISER: Axcan

COMPLAINANT: Ferring

SUBJECT: c02-53 Salofalk detail aid

PRECLEARANCE: Yes in December 2001

ALLEGATIONS: Graphic portrayal of the site of action for the suspension included part of the transverse colon and thus, was not consistent with the approved labelling.

PAAB DECISION: Agreed that the shading extended too far and it was potentially misleading because it did not give an accurate portrayal of where the drug worked.

PENALTY: Cease distribution and Rx&D notified of the PAAB Code violation.

OUTCOME: Axcan agreed to cease distribution of the subject APS.

PAAB staff

Commissioner: Ray Chepesiuk

Senior Reviewer: John Wong

Reviewers: Colin Campbell
Pauline Dong
Lucia Kim
Yin-Ling Man
Patrick Massad

Submission Co-ordinator: Carol Johnston

Administration Support: Estelle Parkin

Accounts: Glenn Golaz

All can be reached at (905) 509-2275.

Who makes up the "Board" in PAAB?

Fédération des médecins spécialistes du Québec
Canada's Association for the Fifty-Plus (CARP)
Canadian Association of Medical Publishers
Canadian Drug Manufacturers Association
Canadian Medical Association
Canada's Research-Based Pharmaceutical Companies
Canadian Pharmacists Association
Consumers' Association of Canada
Association of Medical Advertising Agencies
Nonprescription Drug Manufacturers Association
Advertising Standards Canada
Chair Dr. R. Perkin
Past Chair Dr. J. Godden
Treasurer L. Biondi

Health Canada is an ex-officio observer

PAAB: need more info?

PAAB is an independent review agency whose primary role is to ensure that advertising of prescription drugs is accurate, balanced and evidence-based. The scope of the PAAB Code currently includes advertising of prescription and OTC products to health professionals, in all media.

Key activities of PAAB include:

- *Maintaining the Code of Advertising Acceptance, which is approved by representatives of member organizations*
- *Review advertising prior to publication, to ensure claims meet Code standards. The scope of the Code currently includes advertising of prescription and OTC drug products to health professionals, in all media.*
- *Training, adjudicating complaints, administering penalties, reporting of infractions, and other activities to encourage compliance.*
- *Advising clients about Direct-to-Consumer Advertising regulations regarding prescription drugs*

For information or if you have comments:

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Executive Committee

Chair	Dr. Reg Perkin
Vice-Chair	Gloria Bowes
Treasurer	Lorenzo Biondi
Member	John Suk
Member	Ken Stallman
Commissioner	Ray Chepesiuk

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CCPP