Pharmaceutical Advertising Advisory Board **July 2001**

PAAB UPDATE

Quarterly Information Bulletin

PAAB
ACTIVITIES DURING THE
SECOND QUARTER OF 2001

Year 2001 marks the 25th operating year of drug advertising review for 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.

Annual/General Meeting

The PAAB Annual/General Meeting of Directors was held Friday, April 20, 2001 at the College of Family Physicians in Mississauga, Ontario.

- After consultation from doctors, pharmacists and the pharmaceutical industry on the subject of using abstracts and poster presentations as references for advertising claims, the Board members agreed to revise the PAAB Code. Several sections were revised to not allow the use of abstracts as reference support for advertising claims. Please see the PAAB Advisory on our web-site for details of these Code amendments.
- The Fédération des médecins spécialistes du Québec (FMSQ) became a voting member of the PAAB. Dre. Francine Mathieu-Millaire is their representative.
- PAAB Treasurer Lorenzo Biondi reported that the Auditor's Report spoke well of the PAAB financial situation and this could support the addition of a Reviewer position as well as office space expansion.
- The Members agreed that no administrative action relevant to Direct-to-Consumer advertising was imminently needed.

New Health Canada Guidelines

In April 2001, Health Canada released the *Therapeutic Comparative Advertising Directive and Guidance Document* authored by the Advertising Issues Working Group of the Bureau of
Licensed Product Assessment. Part I is the *Principles for Comparative Claims Related to the Therapeutic Aspects of Drugs*, a directive that is applicable to all drugs for human use regardless of the intended audience (health professionals or consumers). It includes the roles and responsibilities of the independent advertising preclearance agencies, advertising sponsors and the Therapeutic Products Directorate. Part II consists of the Guidance Document *Data Requirements to Support Comparative Claims Related to the Therapeutic aspects of Nonprescription Drugs Used in Consumer-Directed Advertising and Labelling* that outlines the

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data requirements to support consumer-directed nonprescription drug comparative advertising and labelling. You can see the document on the Health Canada web-site.

Get DTCRx Advice

We remind you that PAAB will give an advisory opinion on specific projects in print, broadcast or Internet, 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. For a fee, we can assist you in interpreting Health Canada guidelines on what is advertising and what is not considered to be advertising. PAAB will charge its regular review fee for written opinions. Advertisers should note that the PAAB members have agreed to the Health Canada request that it be copied on submissions reviewed by the PAAB.

PAAB Workshops

We get requests for information about PAAB workshops. The PAAB will conduct onsite meetings or mini-workshops for individual pharmaceutical companies or advertising agencies on request, for a fee of $350 plus travel expenses. Contact the Commissioner for more information.

Subscribe to PAAB News

The PAAB web-site will soon allow you to add your name to an e-mail address list that will allow you to get information that has been added to the PAAB Web-site automatically. Please check our web-site for this new service.

"In Press" References

Occasionally companies ask the PAAB to accept statements based on an article that was accepted by a publisher for publication at a future date. This has been deemed to be an acceptable practice, done on trust. However, we have had two recent examples of companies presenting an "accepted" manuscript that differed significantly from the published article. If more examples occur, the PAAB will have to revise its policy.

Review Activity

During the period of April 1 to June 30, 2001, the total number of submissions reviewed was 649 APS comprised of 631 human and 18 veterinary. This compared to 653 (640/13) during the same period of 2000. Detail Aids comprised 46% of the overall activity.

During the first half of 2001, 84%of APS were given a first review response in 10 days or less. The PAAB Commissioner apologizes for any inconvenience caused to those advertising sponsors affected by first review time greater than ten days, mostly in the months of March and May. The PAAB review staff are working to improve the efficiency for first review response. To help improve the turnaround time, the PAAB Commissioner asks sponsors and their agencies to respect the PAAB Code when advertising is being created.

Be Part of the PAAB Review Team

The PAAB is currently seeking candidates for the position of Assistant Commissioner/Reviewer. You must have a depth of knowledge in pharmacology, a broad scope of knowledge in clinical therapeutics and be able to work in English and French. You can send your resume to PAAB Commissioner Ray Chepesiuk.

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 or unauthorized products are sent without delay to Health Canada for investigation.

Code Section 9 contains a guide for the resolution of complaints against pharmaceutical advertising that is subject to review by the PAAB. Organizations are encouraged to act in the spirit of the Code to seek resolution and abide by those terms, even in specific situations which are not directly anticipated in section 9.

PAAB COMPLAINT REPORT

Period: April 1 to June 30, 2001

During the period of April 1 to June 30, 2001, the PAAB Commissioner processed 15 **Stage 2 complaints**. PAAB reviewed 631 advertising pieces during the same period.

Of the 15 complaints, 8 were generated from advertising that had been previously PAAB-reviewed One was completely sustained, one was referred to Health Canada because of safety allegations, three were rejected completely and three had some allegations rejected. Based on the number and the nature of the complaints, it appears that the pharmaceutical industry is asking the PAAB for a tighter interpretation of the PAAB Code. Of the 7 complaints on advertising that were not PAAB-approved, four were sustained, one rejected and two were referred to Health Canada.

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 4 notice of violation letters in the second quarter of 2001.

Update of case of non-compliance with a PAAB complaint ruling – In the January 2001 UPDATE, we reported that complaint ruling File # c00-55 regarding Taro Taro-Warfarin advertising was referred to Health Canada because Taro chose not to comply with the PAAB ruling. This was the first case of non-compliance with a PAAB complaint ruling since the complaint procedure was revised in 1996. In summary, the Health Canada letter stated "*It appears clear, based on the statements and evidence provided by the Commissioner that Taro has made promotional representations that are not supported by the current Product Monograph. Thus the relevant promotional material used by Taro would be misleading and would violate section 9(1) of the Food and Drugs Act. … Taro Pharmaceuticals is requested to cease distribution of violative ads immediately and to submit revisions to Taro-Warfarin advertising material directly to the PAAB.*"

STAGE TWO DECISIONS

1. ADVERTISER: Novartis

COMPLAINANT: Pfizer

SUBJECT: c01-09 Exelon Journal ad and detail aid

PRECLEARANCE: Yes

ALLEGATIONS: Two allegations: 1) Dual action claim is misleading. 2) Adverse events are understated

PAAB DECISION: **Rejected**. The content and context of the statements appear to be consistent with the presentation of the information in the Product Monograph.

2. ADVERTISER: Wyeth-Ayerst

COMPLAINANT: GlaxoSmithKline

SUBJECT: c01-14 Effexor Detail Aid

PRECLEARANCE: Yes

ALLEGATIONS: Four allegations – 1) Claims for Effexor based on Poirier paper conflict with previous PAAB complaint ruling and do not have balancing copy to express the limitations of the Poirier data (s3.5). 2) Use of statements to summarize two clinical trials in which two different venlafaxine formats were studied. 3) Claims based on both Effexor formulations and only providing disclosure of the safety profile and dosing of one of the two molecules. 4) Ambiguity of term "remission" requires definition in advertising.

PAAB DECISION: This is the second time gsk has complained about statements based on the Poirier study in Effexor advertising. Allegations 2 and 4 were **sustained** and allegations 1 and 3 were **rejected**.

PENALTY: Minor adjustments to this advertising are required. Replacement material should be ready by September 1, 2001.

OUTCOME: No objection stated.

3. ADVERTISER: DuPont

COMPLAINANT: Taro

SUBJECT: c01-16 Coumadin journal ad

PRECLEARANCE: Yes

ALLEGATIONS: Emphasis on INR testing when products are switched is misleading and not necessary when patients are switched to Taro-Warfarin. Taro alleges this is a scare tactic.

PAAB DECISION: **Rejected**. DuPont message is consistent with the Health Canada approved Product Monograph. The message advocates INR testing which is consistent with current medical practice and thus is not a scare tactic. This was further confirmed by the Health Canada ruling that Taro Taro-Warfarin advertising was not consistent with the approved Product Monograph and may potentially compromise patient safety.

4. ADVERTISER: Paladin Labs

COMPLAINANT: Wyeth-Ayerst

SUBJECT: c01-26 Plan B journal ad

PRECLEARANCE: Yes

ALLEGATIONS: Visuals are "identical" to those used in current Triphasil advertising.

PAAB DECISION: **Rejected**. Although there are similar components i.e. sperm swimming away from something, the colours and layout are different

5. ADVERTISER: Novartis

COMPLAINANT: Merck Frosst

SUBJECT: c01-32 Diovan service vehicle ad

PRECLEARANCE: Yes

ALLEGATIONS: Three allegations: 1) Provision of a consumer magazine attached to an advertisement violates s6.4 and if left in doctors' waiting rooms may be illegal Direct-to-Consumer advertising 2). Prescribing information did not meet Code requirement. 3) Superiority claims are misleading

PAAB DECISION: 1) **Sustained**. Although this item was accepted during preclearance review as presented in good faith by Novartis, some confusion was present because it was not clear to the reviewer that an actual consumer magazine was being given away in previous review that was similar to this case. The PAAB commissioner believes that this would be a violation of the Rx&D Code of Marketing Practices and thus should not be accepted by the PAAB. 2) **Rejected**. Prescribing Information was presented in a manner that met PAAB Code requirements. 3) **Deferred** because this allegation was part of another complaint lodged by Merck Frosst.

PENALTY: Appears to be one-time special promotion by Novartis and misinterpretation of the material at the PAAB led to acceptance. Novartis should retrieve the distributed items if they were left in doctors' waiting rooms.

OUTCOME: Agreed.

6. ADVERTISER: Eli Lilly

COMPLAINANT: Janssen-Ortho

SUBJECT: c01-36 Zyprexa journal ads and sales aids

PRECLEARANCE: Yes

ALLEGATIONS: New evidence has appeared in the form of published articles that challenge the wording of the superiority claims, based on the Tran study, for Zyprexa over Risperdal.

PAAB DECISION: New information has become available. **Sustained** because of recent publication of another comparative study that is not consistent with the results of the Tran study, published weaknesses in some statistical analysis of the Tran study, and recent knowledge of optimal dosing of Risperdal, supported by Health Canada opinion, that is not reflected in the Tran study. Statements based on the results of the Tran study in advertising should not imply or state proven superiority versus Risperdal and should reflect current medical thinking and the Health Canada approved product monographs.

PENALTY: August 15, 2001 deadline to cease distribution and modify existing advertising. Zyprexa superiority to Risperdal claims should not be emphasized by Eli Lilly because they are not proven based only on the Tran study.

OUTCOME: Agreed.

7. ADVERTISER: AstraZeneca

COMPLAINANT: GlaxoSmithKline

SUBJECT: c01-37 Zomig journal ad

PRECLEARANCE: Yes

ALLEGATIONS: 30 minute relief claim does not have sufficient evidence.

PAAB DECISION: **Sustained**. Claim of relief would require evidence of a 2 point scale drop. Claim should be "improvement" not relief.

PENALTY: Revise material within two months

OUTCOME: Agreed.

8. ADVERTISER: Eli Lilly

COMPLAINANT: Janssen-Ortho

SUBJECT: c01-38 Zyprexa FaxBulletin letter

PRECLEARANCE: No

ALLEGATIONS: Unsolicited fax mailing requires preclearance and contains misleading comparative claims.

PAAB DECISION: Mailing appears to be retaliatory because of a perceived unfair attack on Zyprexa through a Janssen-Ortho press release that was not subject to PAAB preclearance. **Sustained** because it is Zyprexa focussed advertising.

PENALTY: Notified Rx&D of violation of their Code and therefore, Eli Lilly will receive a fine. The PAAB encourages all companies and the publishers of fax services to respect the preclearance requirements of the PAAB Code.

OUTCOME: Eli Lilly did not agree with the PAAB ruling. However, based on their letter, there appears to be a difference of opinion with the PAAB regarding current advertising regulations.

9. ADVERTISER: Boehringer Ingelheim

COMPLAINANT: Merck Frosst

SUBJECT: c01-39 Mobicox Patient material

PRECLEARANCE: No

ALLEGATIONS: Requires preclearance and statements are not in compliance with previous Health Canada ruling. May also be a violation of Food & Drugs Act that prevents Direct-to-Consumer advertising of Prescription drugs except for name, price, quantity.

PAAB DECISION: **Sustained**. Patient information that is consistent with the "Information to the Consumer" section of the Product Monograph is exempt from PAAB preclearance review. This material contained promotional claims.

PENALTY: BICL should retrieve existing distributed material from doctors' offices. Referred to Rx&D for a fine due to breach of Rx&D Code of Marketing Practices.

OUTCOME: BICL instructed their field representatives to retrieve distributed items where possible. Merck Frosst sent a list of offices where their representatives noticed the pamphlets in waiting rooms.

10. ADVERTISER: Janssen-Ortho

COMPLAINANT: Pfizer

SUBJECT: c01-44 invitation for meeting

PRECLEARANCE: No

ALLEGATIONS: Pre-NOC advertising of Reminyl

PAAB DECISION: Referred to Health Canada in accordance with their policy regarding pre-NOC promotion

11. ADVERTISER: Boehringer Ingelheim

COMPLAINANT: Merck Frosst

SUBJECT: c01-45 Doctor Letter signed by BICL Medical Director

PRECLEARANCE: No

ALLEGATIONS: Promotional letter requires preclearance

PAAB DECISION: Letter was unsolicited promotion of Mobicox. BICL argued that they sent material to

three doctors to correct the information they gave at presentations. Merck Frosst provided documentation that the physicians did not request the material and were offended by the BICL action.

PENALTY: Referred to Rx&D for fine because of violation of sections 2.2 and 2.4 of Rx&D Code of Marketing Practice.

OUTCOME: In a follow-up letter BICL disagreed with the PAAB ruling. Boehringer Ingelheim states the PAAB is "stifling an effort to further the scientific debate in the area of COX-2 inhibition, and as such cannot accept the ruling." BICL states they were not advertising to those doctors, they were providing unsolicited information to correct a misunderstanding the doctors had about their product Mobicox.

12. ADVERTISER: Merck Frosst

COMPLAINANT: Boehringer Ingelheim

SUBJECT: c01-47 Vioxx detail aid

PRECLEARANCE: No

ALLEGATIONS: Representative created promotion of Merck Frosst products listed on the Saskatchewan Formulary and included off-label use for Vioxx

PAAB DECISION: **Sustained**. Requires preclearance and off-label promotion is violation of Food & Drugs Act.

PENALTY: Commissioner notes that BICL had made Health Canada aware of the Food & Drugs Act violation.

OUTCOME: Merck Frosst advised the PAAB that they took appropriate remedial action with respect to the field representatives that initiated the creation and distribution of this advertising material and they have provided a compliance message for all of their field representatives. Merck Frosst will retrieve, where possible, the distributed items from pharmacies.

13. ADVERTISER: Merck Frosst

COMPLAINANT: Boehringer Ingelheim

SUBJECT: c01-52 Vioxx Detail Aid

PRECLEARANCE: Yes

ALLEGATIONS: Claims compromise patient safety

PAAB DECISION: **Referred** to Health Canada in accordance with their policy regarding patient safety being potentially compromised by drug advertising.

14. ADVERTISER: Merck Frosst

COMPLAINANT: Boehringer Ingelheim

SUBJECT: c01-49 Priority press Meeting Report

PRECLEARANCE: No

ALLEGATIONS: Meeting Report based on a meeting controlled by the Canadian Rheumatology Association was Vioxx advertising that required PAAB preclearance. The report contained misleading claims.

PAAB DECISION: **Rejected**. This Priority Press Meeting Report was consistent with company policy that was based on PAAB meeting report exemption guideline. Priority Press had been producing reports such as this for twelve years and the PAAB has been fully informed of their publishing policy. Merck Frosst involvement was limited to financial sponsorship of the distribution.

15.
ADVERTISER: Ferring

COMPLAINANT: Axcan

SUBJECT: c01-62 Meeting Report and accompanying letter

PRECLEARANCE: No

ALLEGATIONS: Meeting appeared to be Ferring controlled and the report was advertising of off-label claims for 5-ASA (Pentasa)

PAAB DECISION: **Sustained**. Report did not appear to meet the PAAB exemption guideline and thus required preclearance. Also, there appears to be promotion of 5-ASA as safe and effective in the prevention of colorectal cancer, an off-label claim. The Commissioner referred this file to Health Canada

because of the potential safety issue of promoting 5-ASA as safe and effective for prevention of colorectal cancer, a claim not approved by Health Canada.

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