Pharmaceutical Advertising Advisory Board **April 2002**

PAAB UPDATE

Quarterly Information Bulletin

PAAB
ACTIVITIES DURING THE
FIRST QUARTER OF 2002

Year 2002 marks the 26th year of drug advertising review 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.

Help Wanted

The PAAB has an opening for a Reviewer. You are an innovative individual with strong scientific analytical and research assessment skills. Working as part of a team, you are well-organized with excellent interpersonal skills. Qualifications include: a university degree in pharmacy or equivalent scientific studies; bilingual (English and French); computer literacy. Experience in medical information, regulatory affairs or pharmaceutical marketing is an asset. Competitive salary and benefits based on experience. Please contact Commissioner Ray Chepesiuk at the PAAB.

Annual/ General Meeting

The next PAAB Annual and General Meetings of Members and Directors will be held Friday, April 12, 2002 at the College of Family Physicians in Mississauga, Ontario.

Get DTCRx Advice

We remind you that PAAB will give a written advisory opinion on specific projects that involve advertising or information directed at the general public regarding prescription drugs. Currently, companies cannot advertise prescription drugs except for name, price, and quantity or treatments of schedule A diseases to the general public. We can assist you in interpreting Health Canada guidelines on what is advertising and what is not considered to be advertising. 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.

Faxed Advertising

We remind advertisers that faxed advertising communications to health professionals are not exempt from the PAAB Code of Advertising Acceptance. Commercial messages appearing alone (price change, formulary listing, new package size, out of stock messages) are exempt from PAAB review in any publication. Note any inclusion of product claims (therapeutic, economic, QOL, merit) requires PAAB review and **inclusion of prescribing information** with the fax distribution.

LOOK INSIDE

Code Revision – Patient Education

At the November 9, 2001 Board Meeting the PAAB Directors approved the following Code revision.

> Section 6.6f will read as '*Patient Information direct from and consistent with the product monograph [see 6.4 for regulations]*'.
> Section 6.4 will read as '*Service-oriented vehicles are designed to contribute to the healthcare professional's/ patient's understanding of a condition or its treatment. Such materials include Educational APS and patient information [see 6.6f for exemptions] that are prepared or controlled by the manufacturer of its agent [11.10]*'.
> Section 6.4.2 will read as '*Examples of patient information vehicles are company-controlled patient brochures, internet and other electronic presentations, and 1-800 number scripts.*'
> Newly created Section 6.4.3 will read as '*Company controlled or prepared patient information is information that contains editorial material that is in addition to the patient information section of the product monograph*'.

You should note that this is a clarification of the current wording to show the necessity of formal review of company created and/or controlled patient material distributed through health professionals. It does not cover items created under the full control of a third-party organization such as a patient advocacy association. Other exemptions include information as part of a subscription compliance program and internet sites specifically directed at patients with no healthcare professional intermediary distribution. The members agreed to an implementation date of April 1, 2002. We look forward to your full cooperation with the PAAB Code of Advertising Acceptance.

Review Activity

During the period of January 1 to March 31, 2002, the total number of human and veterinary drug advertising submissions reviewed was 777. This was an above average volume compared to 677 during the same period of 2001.

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

During the first quarter of 2002, 47% of the submissions were given a first review response in five days or less and 100% were given a first review response in 10 days or less. For all of 2001, the turnaround to first review in five days or less was 42%. A high volume, a workload more weighted towards detail material and some particularly combative advertisers contribute to hindering the efficiency. We are continuing to see more than the average number of product launches and many in particularly competitive therapeutic areas. The PAAB Commissioner notes that the appeals he has seen about unacceptable claims and support material that most stakeholders view as unethical, indicate a need for increased regulatory and scientific training of pharmaceutical marketers.

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.

Please see Code section 9 for complete details of the three stage process.

PAAB COMPLAINT REPORT

Period: January 1 2002 to March 31, 2002

During the period of January 1 to March 31, 2002, the PAAB Commissioner ruled on 6 **Stage 2 complaints**, of which 5 were initiated in 2001. PAAB reviewed 777 advertising pieces during the same period.

Of the 6 complaints, 2 were generated from advertising that had been previously PAAB-reviewed. Both complaints were sustained. Of the 4 complaints on advertising that were not PAAB-approved, all four were sustained. One had been sent to Health Canada for a product monograph interpretation. In July 2001, we had sent a request for Health Canada investigation into a complaint re. a Dermik Noritate (Metronidazole topical) APS because of non-compliance with a PAAB ruling. Health Canada notified the PAAB in March 2002 that action had been taken and the company would stop the violative advertising.

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 and/or when appropriate, the PAAB will notify the advertiser's trade association and/or Health Canada for their assessment of additional penalties. PAAB sent 7 notice of violation letters in the first quarter.

STAGE TWO DECISIONS

1.
ADVERTISER: Byk /Solvay

COMPLAINANT: Abbott

SUBJECT: c01-43 Pantaloc (pantoprazole) APS registered December 20, 2001

PRECLEARANCE: yes

ALLEGATIONS: The tagline "No Known Drug Interactions" was not consistent with the Product Monograph that had been revised since the inception of the statement (s3.1).

PAAB DECISION: Verbatim – "The main issue is the claim "No known drug interactions". My review of the current Pantaloc Product Monograph does reveal stated interactions. Therefore, the advertising statement is not true. The PAAB should not accept this claim in advertising. I do note that this statement was first approved by the PAAB when, in fact, the Product Monograph did not include any stated drug interactions. This is a dynamic business and Byk/Solvay should adjust their advertising statements when changes in Product Monographs take place."

PENALTY: Cease distribution of 13 Advertising /promotional systems. Inform sales representatives directly of this ruling.

OUTCOME: Byk/Solvay agreed to cease distribution and submitted an action plan to the satisfaction of the PAAB Commissioner.

2.
ADVERTISER: Dermik

COMPLAINANT: Schering

SUBJECT: c01-55 Dermatop registered June 6, 2001

PRECLEARANCE: No

ALLEGATIONS: Advertising was not precleared (s6.3) and the comparison to Schering Elocom (mometasone furoate) regarding pediatric use was misleading(s2.1, s3.1)).

PAAB DECISION: To resolve the pediatric use allegation, the PAAB requested an opinion from Health Canada in June 2001 regarding inclusion of statements regarding pediatric use in the Elocom product monograph. The response was received in February 2002. The APS was seen as misleading due to the presentation of the pediatric indication comparison.

PENALTY: Dermik should immediately cease distribution of this APS. Dermik should recall any outstanding APS in the possession of their representatives. Dermik should notify their representatives that the comparative claim regarding pediatric use is considered to be misleading by Health Canada and the PAAB. Please copy the PAAB. To help their compliance with the PAAB Code, Dermik should send future advertising to the PAAB for preclearance review.

OUTCOME: Dermik complied with the ruling.

3.
ADVERTISER: Pharmacia

COMPLAINANT: Boehringer-Ingelheim

SUBJECT: c01-76 Celebrex (celecoxib) Statgram letter registered September 2001

PRECLEARANCE: No.

ALLEGATIONS: This advertising should have been precleared by the PAAB (s6.2)

PAAB DECISION: Pharmacia stated this letter was related to a safety issue of which they had made Health Canada aware. Thus, PAAB preclearance was not necessary. Due to a difference of opinion with Pharmacia, the PAAB requested a Health Canada opinion regarding the regulatory status of this item. Based on the letter received by the PAAB in January 2002, Health Canada ruled that the item was advertising and not related to an imminent safety issue.

Health Canada stated this letter was not developed in collaboration with them.

PENALTY: Cease further distribution and send future Statgram letters to the PAAB for preclearance. To initiate a fine, PAAB sent notice to Rx&D of violations of s2.1 and 2.4 of the Rx&D Code of Marketing Practices.

OUTCOME: The fine was assessed by Rx&D

4.
ADVERTISER: Bayer

COMPLAINANT: Pfizer

SUBJECT: c01-83 Avelox (moxifloxacin HCl) Detail Aid registered January 10, 2002

PRECLEARANCE: Yes

ALLEGATIONS: Claim of "Avelox Works Fast" is misleading due to absolute nature of "works" and insufficient support by the Kries et al reference.

PAAB DECISION: Agree that the Kries paper did not have sufficient controls to qualify as evidence for support of the claim in advertising. However disagree with Pfizer that the claim "Avelox works fast" was misleading because it is accompanied by qualifying statements to clarify what is meant by "fast".

PENALTY: Cease distribution of all APS using the Kries study as a reference.

OUTCOME: Bayer complied with the ruling.

5.
ADVERTISER: Serono

COMPLAINANT: Biogen

SUBJECT: c01-89 Rebif (interferon beta-1)

PRECLEARANCE: No

ALLEGATIONS: Distribution of APS with claims based on the EVIDENCE study were misleading because the study has not been peer reviewed and published in a reputable medical journal. Also items of this nature should be precleared by the PAAB.

PAAB DECISION: Agree with Biogen that preclearance review would be required and that the unpublished report would not be sufficient evidence to support claims in advertising.

PENALTY: Cease unsolicited distribution effective immediately and order representatives to return all outstanding copies to the head office.

OUTCOME: Serono complied with the ruling.

6.
ADVERTISER: Pharmacia

COMPLAINANT: Merck Frosst

SUBJECT: c02-11 Celebrex (celecoxib) advertisement placed in the midst of a single-sponsor editorial supplement "Action Clinique" about use of coxibs to treat arthritis in L'Actualite Medicale". Registered March 7, 2002

PRECLEARANCE: No

ALLEGATIONS: placing the advertisement in the supplement and the Item was advertising and should be precleared by the PAAB.

PAAB DECISION: Agree with Merck Frosst based on s2.1 and Health Canada published policy on linkage of non-branded information and branded advertising.

PENALTY: Sent notice of violation to Rx&D for fine to be assessed.

OUTCOME: Pharmacia registered a Stage 3 appeal on March 25, 2002

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.

For information or if you have comments:

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The PAAB Code of Advertising Acceptance and PAAB Supplementary Guidelines are available from the PAAB office or www.paab.ca