

PAAB UPDATE

Quarterly Information Bulletin

PAAB ACTIVITIES DURING THE THIRD QUARTER OF 2001

Year 2001 marks the 25th operating year 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, call the PAAB office for copies or 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 General Meeting

The next PAAB General Meeting of Directors will be held Friday, November 9, 2001 at the College of Family Physicians in Mississauga, Ontario. Topics to be discussed include a revision to the PAAB Code of Advertising Acceptance to clarify the submission review requirement for patient information distributed through health professionals and a potential fee increase for 2002.

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 meeting or written review 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.

With respect to DTC regulations, this service includes review of "patient information" that goes beyond the information provided in the "Information to the Consumer" section of the Product Monograph. Commissioner Chepesiuk anticipates a rewording of the Code of Advertising Acceptance to reflect the intent of preclearance review of these items.

The PAAB Expands Its Resources

Commissioner Ray Chepesiuk is pleased to announce that Ms. Sara Hayward will join the PAAB as a sixth Reviewer in October 2001. Sara is a pharmacist that has worked in community pharmacy at the store and management levels in New Brunswick and Ontario. In July 2001, the PAAB added 1400 sq. ft. to its office facilities in Pickering, Ontario to accommodate the increased workload it has recently seen.

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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.

PAAB Commissioner will speak about the PAAB as part of the OPMA Education Day in Mississauga on October 24, 2001.

Subscribe to PAAB News

You can add your name to an e-mail address list on the PAAB Web-site. 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.

Time Savers

In August 2001, the PAAB staff struggled to stay under the ten day limit for turnaround to first review and we apologize for that. We believe that the situation has been addressed because during September 100% of first reviews were turned around in 10 days or less and half of those were in 5 days or less.

There are some things that you can do to help us process your advertising reviews quicker:

- Companies should ensure that their medical departments are signing off on APS before they get to the PAAB. Some agencies are sending "trial balloons" to the PAAB.
- If you revise advertising during the PAAB review process, please notify us in writing of the changes. It wastes time if we have to review the complete piece each time it comes in due to lack of trust of some sponsors.
- Contact the Reviewers for specific points of clarification prior to sending back revised copy.
- Contact Submission Coordinator Carol Johnston and not the Reviewers to see where your file is in the PAAB process.

Review Activity

During the period of July 1 to September 30, 2001, the total number of submissions reviewed was 693 APS comprised of 686 human and 7 veterinary. This compared to 645 (626/19) during the same period of 2000. Detail Aids comprised 51% of the overall activity.

During the first three-quarters of 2001, 89% of APS were given a first review response in 10 days or less.

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: July 1 to September 30, 2001

During the period of July 1 to September 30, 2001, the PAAB Commissioner processed 7 **Stage 2 complaints** related to human drug ads. PAAB reviewed 686 advertising pieces during the same period.

Of the 7 complaints, 2 were generated from advertising that had been previously PAAB-reviewed and approved. Both were rejected. Of the 5 complaints on advertising that were not PAAB-approved, two were sustained and three were referred to Health Canada. The total stage two decisions for 2001 is 31.

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 third quarter of 2001.

STAGE TWO DECISIONS

1. ADVERTISER: Aventis

COMPLAINANT: Merck Frosst

SUBJECT: c01-33 Altace (ramapril) Sample Package Holder

PRECLEARANCE: No

ALLEGATIONS: Merck Frosst alleges violation of Code s1 in that the item requires PAAB preclearance. Aventis disagrees.

PAAB DECISION: Agreed that it is advertising subject to preclearance review because sample package holders are not considered to be labeling by Health Canada.

PENALTY: Discontinue distribution and submit item for PAAB review

OUTCOME: Aventis agrees to submit item for review.

2. ADVERTISER: AstraZeneca

COMPLAINANT: GlaxoSmithKline

SUBJECT: c01-60 Oxeze Turbuhaler (formoterol fumarate dihydrate) Detail Aid

PRECLEARANCE: Yes

ALLEGATIONS: Issue #1 was a headline that was in juxtaposition to a comparative chart was misleading. Issue #2 was a dosing comparison between Oxeze and Serevent.

PAAB DECISION: Although we did agree that better separation could have been achieved to avoid the gsk interpretation, in both issues the presentation did not appear to be overtly misleading.

PENALTY: \$500 administration fee assessed to gsk.

OUTCOME: No further action.

3. ADVERTISER: Ferring Pharmaceuticals

COMPLAINANT: Axcan Pharma Inc.

SUBJECT: c01-62 Pentasa (5-ASA) Single-sponsor

meeting report

PRECLEARANCE: No

ALLEGATIONS: Item was mailed to Canadian doctors by Ferring and was not precleared by the PAAB (s6.4) and it appears to promote Pentasa for cancer chemoprevention (s3.1).

PAAB DECISION: Allegation of unapproved claims for cancer chemoprevention could compromise patient safety. Therefore, file was sent to Health Canada for investigation.

4. ADVERTISER: Wyeth-Ayerst

COMPLAINANT: GlaxoSmithKline

SUBJECT: c01-67 Effexor XR (venlafaxine) Detail Aid

PRECLEARANCE: Yes

ALLEGATIONS: Issue #1 stated that there appeared to be off-label promotion for anxiety. Issue #2 challenged the claim that generalized anxiety disorder was the most common anxiety disorder.

PAAB DECISION: Issue #1 was rejected because the approved indication of generalized anxiety disorder was mentioned frequently and prominently throughout the APS. Issue #2 was rejected because the claim was supported by current literature and gsk did not provide a current authoritative source to refute it.

PENALTY: Assessed a \$500 administration fee to gsk.

OUTCOME: No further action.

5. ADVERTISER: Dermik Laboratories

COMPLAINANT: Galderma via Health Canada

SUBJECT: c01-69 Noritate (metronidazole topical cream) detail aid

PRECLEARANCE: No

ALLEGATIONS: Claim of "missed dose protection" was misleading and the appearance of promotion of unapproved once-a-day dosing

PAAB DECISION: Case was returned to Health Canada because the claim had been previously rejected by the PAAB and there appears to be willful noncompliance with the PAAB review system.

6. ADVERTISER: Biogen Canada

COMPLAINANT: Teva Neuroscience

SUBJECT: c01-72 Avonex (interferon beta-1a) consumer brochure

PRECLEARANCE: No

ALLEGATIONS: Brochure is advertising that is not exempt from PAAB review and the comparative claims point to Avonex as drug of choice in a misleading manner.

PAAB DECISION: Case sent to Health Canada for investigation in accordance with their policy regarding direct-to-consumer advertising.

7. ADVERTISER: Pharmacia/Pfizer

COMPLAINANT: Boehringer-Ingelheim

SUBJECT: c01-71 Celebrex (celecoxib) posters

PRECLEARANCE: no

ALLEGATIONS: BICL reports sightings in doctors' offices of posters that had been ruled violative by the PAAB based on a Health Canada advisement.

PAAB DECISION: It appears to be the action of a few representatives or leftover material that had resurfaced. Pharmacia provided evidence that existing stock had been destroyed after previous PAAB intervention.

PENALTY: Pharmacia should inform its representatives to retrieve all existing copies of the posters and destroy them.

OUTCOME: Pharmacia provided a copy of the letter that was sent to their representatives.



For information or if you have comments:

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

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

Who makes up the "Board" in PAAB?

Voting Organizations

Nonprescription Drug Manufacturers Association of Canada (NDMAC)
Fédération des médecins spécialistes du Québec (FMSQ)
Canadian Medical Association (CMA)
Canadian Pharmacists Association (CPhA)
Canada's Research-Based Pharmaceutical Companies (Rx&D)
Canadian Drug Manufacturers Association
Canada's Association for the Fifty Plus (CARP)
Canadian Association of Medical Publishers (CAMP)
Consumers' Association of Canada (CAC)
Association of Medical Advertising Agencies (AMAA)
Advertising Standards Canada (ASC)

Individuals

Chair Dr. R. Perkin
Past Chair Dr. J. Godden

Health Canada is an ex-officio observer

PAAB STAFF

Commissioner: Ray Chepesiuk

Senior Reviewer: John Wong

Reviewers/Assistant Commissioners:

Colin Campbell
Yin-Ling Man
Lucia Kim
Pauline Dong
Sara Hayward

Submission Coordinator:

Carol Johnston

Admin Support: Estelle Parkin

Accounts: Glenn Golaz

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