Pharmaceutical Advertising Advisory Board **April 2000**

PAAB UPDATE

Quarterly Information Bulletin

PAAB
ACTIVITIES DURING THE
FIRST QUARTER OF 2000

Year 2000 marks the 24th 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.

Reconsider "Fair Balance"

During the past year at over a dozen PAAB workshops/presentations at companies and open forums, Commissioner Ray Chepesiuk has informed advertisers of the requirement for "fair balance" in sections 2.4 and 3.5 of the PAAB Code of Advertising Acceptance. He has also instructed the PAAB reviewers to be vigilant with respect to this issue when reviewing drug advertising.

In the past, there has been some misunderstanding about what is the minimum type size for advertising copy text. There is no minimum type size for advertising copy text stated in the PAAB Code of Advertising Acceptance. However, Code section 2.4 states "APS must reflect an attitude of caution with respect to drug usage, with emphasis on rational drug therapy [11.6]. The advertising copy should provide sufficient information to permit assessment of risk/benefit." Explanatory Note section 2.4.1 clarifies that message by stating "The body copy should include reference to the safety profile and clinically significant adverse effects" and Section 2.4.2 states "Special warnings, precautions or use limitations cited in the product monograph should be included in the body copy". Section 3.5 states "APS containing advertising claims or quotations that emphasize only positive features of a pharmaceutical product while ignoring significant negative findings are not acceptable.

Therefore, Commissioner Chepesiuk reminds all advertisers to abandon the use of six point type footnotes to convey safety information that is important in providing a balanced message to prescribers. He asks advertising submitters to respect the advice of the PAAB Reviewers if their intention is to revise their advertising to be compliant with Code sections 2.4 and 3.5. Surprisingly, PAAB reviewers receive a lot of resistance when this issue is raised in advertising.

Look for the New PAAB Logo

The PAAB members have approved a new logo to distinguish Canadian drug advertising that has been reviewed by PAAB. The new logo was introduced in January 2000 and is now available to advertisers to include on advertising that has been cleared by PAAB. Check our Web-site to get the new look logo. Also, call the PAAB office for facsimiles and/or a CD-ROM.

PAAB Advertising Campaign

To encourage health professionals to look for the PAAB logo on advertising, the Canadian Association of Medical Publishers has agreed to run PAAB journal ads bringing attention to the PAAB Web-site as a source of information about drug advertising regulation. The ads also bring attention to the new PAAB logo with its "Made in Canada" look.

PAAB Web-site "Refreshed"

In March 2000, we saw the completion of the new-look PAAB Web-site. The Web-site features the new PAAB logo as the main graphic and is available in both English and French. The main purpose of the Web-site is to disseminate information related to PAAB activities. Anyone can access the latest version of the PAAB Code of Advertising Acceptance and supplemental guidelines.

The site also includes past issues of this quarterly report "PAAB UPDATE" where the reader can find a report on completed Stage Two and Stage Three complaints. We have added internet links to the Web-sites of PAAB members and to the policies web-page of the Health Canada Therapeutic Products Directorate.

If you have suggestions about the content or additional links, please contact Commissioner Ray Chepesiuk.

Internet Advertising

The Commissioner is frequently asked if the PAAB Code covers Internet advertising. This is a reminder that pharmaceutical product advertising intended for health professionals and placed on Internet Web-sites that originate in Canada are subject to the PAAB Code of Advertising Acceptance.

Staff Change

On March 24, 2000 Assistant Commissioner Joanna Rizos left the PAAB to take a position in the Medical Information department of a drug manufacturer. For the past three years Joanna has made a great contribution to the effectiveness and efficiency of the the PAAB preclearance review program. We wish her the best of success in her new position.

A search for a replacement was started in late March.

Review Activity

The first quarter saw a substantial volume of review activity with the majority of the submissions coming in March.

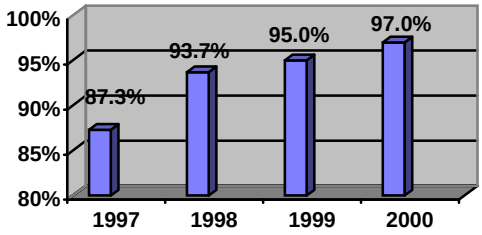
During the period of January 1 to March 31, 2000, the total number of submissions reviewed was 677. This compared to 739 during the same period of 1999, an 8% decrease.

The proportion of advertising vehicles that were submitted for review shows a heavy workload oriented towards detail aid activity (42%).

During the first quarter of 2000, 97% 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.

This meets the Code requirement of ten days for a first review response.

Share of ads with first review in 1- 5 days



PAAB Reviewer Training Session

In March, Dr. Michael Evans from the University of Toronto spent a day with the PAAB review staff discussing current knowledge on Evidence-Based Medicine and, in particular, aspects of critical evaluation of scientific literature that are relevant to pharmaceutical advertising. Included in the discussion was the topic of "fair balance" in advertising (see the lead article in this issue of PAAB UPDATE). He also covered sources of drug information on the Internet that may prove useful to PAAB reviewers. Dr. Evans is a practicing physician and is highly respected for his work in the area of Continuing Medical Education for physicians.

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 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.

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 advertisers 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**. The Stage Two filing letter should be signed by a Senior Company Official. *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: January 1 to March 31 2000

During the first quarter of 2000, the PAAB Commissioner processed 7 **Stage 2 complaints**. PAAB reviewed 677 advertising pieces during the same period.

Of the 7 complaints, 1 was about advertising that had been previously PAAB-reviewed and was sent in by a competitor. That resulted in withdrawal of PAAB's previous acceptance. The 6 complaints on advertising that were not PAAB-approved were sustained and all were referred to Health Canada in accordance with their policy.

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 7 notice of violation letters in the first quarter.

STAGE TWO DECISIONS

1.

ADVERTISER: Wyeth-Ayerst

COMPLAINANT: SmithKline Beecham

SUBJECT: C00-01 Hospital Panel & Reprint Carrier for Effexor XR (venlafaxine)

PRECLEARANCE: Yes

ALLEGATIONS: 4 allegations related to a misleading superiority headline based on data presentations from the Poirier reference (5.5): (1) venlafaxine dose was maximized while paroxetine dose was not, (2) study design favors venlafaxine, (3) misleading response and remission rates based on paroxetine cohort being more severely ill than the venlafaxine cohort, (4) misleading response and remission rates based on mean raw HAM-D scores.

PAAB DECISION: Allegation 1 was upheld and the other 3 were rejected. The claim was originally accepted in an APS prior to 1999 implementation of Code section 5 *Comparisons*. The study limitations stated in the paper were not reflected in the two APS. The headline implied superiority for venlafaxine over paroxetine was proven when indeed the Poirier paper alone was not sufficient to support that claim. The presentation does not meet the requirements of the current Code section 5 *Comparisons*.

PENALTY: Clearance withdrawn for these APS and Wyeth-Ayerst to cease distribution immediately. PAAB will help to expedite approval of replacement material.

OUTCOME: Wyeth-Ayerst replied in writing 18 days after notification by PAAB and agreed to cease distribution of the two APS.

2.

ADVERTISER: Glaxo-Wellcome

COMPLAINANT: Health Professional

SUBJECT: c00-02 public billboard advertising for Zyban (bupropion)

PRECLEARANCE: no

ALLEGATIONS: direct-to-consumer advertising of prescription drug and safety implications associated with use of the product.

PAAB DECISION: Referred to Health Canada with respect to Health Canada policy regarding allegations re public safety.

3.

ADVERTISER: Berlex

COMPLAINANT: DES Action Canada

SUBJECT: c00-06 Diane-35 brochures and public bus shelter and washroom posters.

PRECLEARANCE: no

ALLEGATIONS: violates FOOD & Drugs Act re direct to consumer advertising of a prescription drug

PAAB DECISION: referred to Health Canada because PAAB was informed that HC had received this same complaint.

4.
ADVERTISER: Berlex

COMPLAINANT: Wyeth-Ayerst

SUBJECT: c00-09 patient information brochure for Diane-35

PRECLEARANCE: no

ALLEGATIONS: Direct claim that Diane-35 is an oral contraceptive is not consistent with Health Canada Notice of Compliance marketing authorization or PAAB Code s3.1 (claims consistent with product monograph).

PAAB DECISION: PAAB agreed with complainant based on previous input from Health Canada with respect to the regulatory approval of Diane-35. Berlex disagreed with PAAB ruling. Referred to Health Canada in accordance with Health Canada policy regarding non-compliance with PAAB ruling and promoting an unapproved use.

5.
ADVERTISER: SmithKline Beecham

COMPLAINANT: Rx&D Marketing Practices Review Committee

SUBJECT: C00-11 advertising of rosiglitazone (Avandia) on a company-sponsored educational meeting notice

PRECLEARANCE: no

ALLEGATIONS: pre-Notice of Compliance advertising

PAAB DECISION: referred to Health Canada

6.
ADVERTISER: Glaxo-Wellcome

COMPLAINANT: Health Professional

SUBJECT: c00-12 consumer information brochure for Relenza (zanamivir).

PRECLEARANCE: no

ALLEGATIONS: brochure does not state Relenza has Notice of Compliance with Conditions and that is a requirement of the Relenza product monograph

PAAB DECISION: PAAB agreed with complainant. In addition Commissioner notes that the brochure could be deemed to be advertising because of the addition of a new agent that was not included for balance in the brochure because the new agent did not have a Notice of Compliance when the brochure was created. Glaxo Wellcome (GW) disagreed with complainant allegation that they should state conditional nature of Notice Of Compliance because it may confuse the reader. GW did agree to stop circulation and recall brochures because of the new information that was not included in the brochure. PAAB Commissioner referred the case to Health Canada for an opinion on the necessity of including the fact, that a product was issued a NOC-C, in patient information brochures.

7.
ADVERTISER: Enzymatic Therapy

COMPLAINANT: Health Professional

SUBJECT: c00-16 Journal Ad in --- for CF with IP-6

PRECLEARANCE: no

ALLEGATIONS: Claims of cancer prevention is promotion not authorized by Health Canada and patient safety concerns.

PAAB DECISION: Referred to Health Canada because of pre-authorization claims and public safety concerns.

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