APRIL 2013

PAAB VIEWS

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INSIDE THIS ISSUE

Spring has Sprung

Year 2013 marks the 37th year of the PAAB since its incorporation in 1976. To see the current edition of the PAAB Code, visit the PAAB Web-site www.paab.ca

Ce document est également disponible en français sur notre site web.

MISSION, VISION, VALUES

MISSION: To provide a preclearance review that fosters trustworthy healthcare communications within the regulatory framework.

VISION: Trusted healthcare product communication that promotes optimal health.

VALUES: Integrity, Competency, Credibility, Independence, Excellence, Transparency

PAAB OFFICE RELOCATION

We are still getting some people going to our previous office location for meetings. Please note we are at 1305 Pickering Parkway, Suite 300 in Pickering, Ontario. The phone numbers and fax number will remain the same.

The office can be reached by the 401 and the Pickering GO train station is a five minute walk away.

CODE BOOKS AND APP

You can get copies of the July 1 code revision in booklet form from the PAAB office at $5 each.

You can get the new PAAB Code app at the Apple Store for IPad and from the PAAB website for web browser. There is no cost for the electronic app. It includes the code, advisories and guidances in English and French.

PAAB RESEARCH WITH CLIENTS

The PAAB thanks all clients who participated in the telephone interviews during December and January to help us improve the PAAB.

CODE REVISION UPDATE

On November 23, 2012 the PAAB board approved the revision of the PAAB Code of Advertising Acceptance. There were 4 major areas of the code that received extensive stakeholder consultation and comment: a) evidence basis for claims b) prescribing information/ fair balance c) electronic media s6.5 d) specific nonprescription issues**. Implementation is July 1, 2013 with full transition by July 1, 2014.** Health Canada was part of the consultation.

Implementation July 1, 2013

Please note we have made an update in explanatory note 7.3.2.a. The revision will provide clients with more flexibility when deciding on how to present the required link to the full product monograph.

- *The TMA and the risk communication on the Health Canada website. The requirement relating to the TMA can be met by linking to the appropriate database search page (e.g. the Drug Product Database, Licensed Natural Health Products Database). This option may not be available for new products or those having recently undergone TMA revision due to Health Canada delays in posting which are beyond the advertiser's control. The requirement relating to the risk communication can be met by linking to the MedEffect Canada page.*

Staff will answer specific code questions on the phone. Code Books are available from the PAAB office at $5 each. Code App is available for Ipad at the Apple Store and in PC on the PAAB website (works in browsers at no charge).

PAAB SPEAKS

The PAAB is recognized as a world leader in pharma advertising regulation and guidance. Commissioner Chepesiuk has spoken in Canada, United States and Europe on digital marketing activities. The Commissioner and Chief Review Officer Patrick Massad are available for presentation by invitation.

In April, Commissioner Chepesiuk will present at the EyeforPharma Patient Centricity conference and the EXL Pharma Digital Health Conference. CRO Patrick Massad will present at the EXL Pharma Digital Health Conference and the EyeforPharma Sales Excellence Conference in June.

PAAB staff can conduct learning sessions about the PAAB and the Code of Advertising Acceptance or Direct-to-Consumer advertising of Rx or biological health products on-site at your workplace. Sessions are usually 2 hours long and the content can be tailored to your needs. Q&A about your confidential marketing situations can be discussed. There is a fee and travel expenses charge. See the web-site www.paab.ca for fee info.

Contact Chief Review Officer Patrick Massad for details and fee information 905-509-2275.

PAAB WORKSHOPS

The PAAB conducted workshops in Montreal and Toronto in February 2013. They were a huge success with a vast majority stating that objectives were met. Jon Gwillim was in charge of the marketing for the event and has reported the following marketing campaign stats:

Emails:
Roughly 10,000 emails were sent as part of the awareness / content campaign.

Website: www.paabtraining.com
17,458 visits
40,268 page views

Banner ad campaign
4,765 impressions
964 clicks

Paying delegates:
168 in Montreal
293 in Toronto

The mix of presenters from the PAAB staff and from industry were well received. I thank Jon Gwillim and Kate Eversole for organizing and presenters Patrick Massad, Jennifer Carroll, Karen Rizwan, Terry Cully, Deirdre Cozier, Dr. Fran Paradiso-Hardy. Dr. John Reeves did an excellent job as facilitator.

In early March the PAAB conducted five free webinars covering all aspects of the code changes. Questions were answered. I thank Patrick Massad, Jennifer Carroll, Karen Rizwan, Maxine Armstrong, Laurie Johns and Glenn Golaz for their participation. Big thanks to Dan Hageman and Al Burkin for technical assistance.

REVIEW ACTIVITY

During the period of January 1 to March 31, 2013, the total number of first review submissions was 1,757 files with 20 files going more than 10 days on first review. In the same quarter 2012 the PAAB reviewed 1,955 new submissions. The average of turnaround for first review was 6.9 days. The reviewers averaged 2.2 days for turnaround on revision.

The PAAB can generate a report to show how long the client holds a file vs. the PAAB during the review process to acceptance. In 2012, on average the PAAB has held the file 3.7 days vs. the client holding it 11.4 days.

15% of accepted files took more than 3 revisions to complete in 2013 versus 14% in 2012.

"I felt that all of the topics noted on the agenda were addressed effectively"

- ***TO participant***

"Great use of examples and case studies, very helpful in understanding changes."

- ***TO participant***

PAAB continues to be busy handling submissions files.

RISK MANAGEMENT TOOLS UPDATE

The PAAB has received some inquiries about risk management tools for a specific product. These are sometimes created by the corporate head office in another country, with no specific guidance regarding Canadian advertising regulations. Companies have told us that Health Canada reviews these documents and so we asked Health Canada for an opinion on a specific document. Further to our advice in the January *PAAB Views* we have had additional discussions with Health Canada.

Health Canada reviews some of these tools but from a different perspective than PAAB. Risk management tools are reviewed by Health Canada from a clinical and scientific perspective (not from an advertising perspective). Health Canada states that the PAAB should still review the tools for consistency with the advertising regulations (or to ensure that the tool is exempt from advertising requirements). Risk management tools undergoing Health Canada review should be submitted to PAAB only after completion of the Health Canada review.

Manufacturers should exercise caution when summarizing study results as this has the potential to provide an inaccurate or incomplete picture and may introduce some bias, which could then render the material promotional.

"Health Canada recommends that PAAB continue to review all risk minimization / mitigation/management tools *to help manufacturers comply with the legislative and regulatory advertising provisions of the Food and Drugs Act and Regulations."*

STATEMENTS INVOLVING FORMULARY CHANGES

Only submissions which include one of the following references will be considered for review:

- Formulary listing (or equivalent provincial document)
- Letter signed by a TMA holder senior official (i.e. director level or higher) stating that the product coverage is expected to be unrestricted OR stating the restriction wording expected to be approved by the province. Final PAAB acceptance will not be provided until the final provincially approved formulary listing has been received and reviewed by the PAAB.

Adding formulary messages to already approved pieces will no longer be accepted as an FYI. This update now needs to be submitted for review.
In cases where coverage is restricted (e.g. limited use, exceptional coverage):

The APS presentation must indicate that restrictions exist (in prominent body copy within the claim or proximal to it).
While different provincial formularies often use different terminology to refer to their coverage status (e.g. Exception Drug Status, Special Authorization, etc.), it is acceptable to use an accurate blanket statement such as "Covered on provincial formulary (special authorization)".
If the manufacturer elects to include coverage codes within the APS, the codes must be accompanied by the corresponding coverage criteria (e.g. inclusion/exclusion criteria), definitions, and notes where applicable. These elements may be included in a footnote.
Check The PAAB web-site for the new advisory and the fee schedule.
Please contact the Administration Staff if you have any questions 905-509-2275.

Include the formulary reference(s) at the time of the submission

PAAB COMPLAINT REPORT

During the period of January 1 to December 31, 2012, the PAAB Commissioner processed 1 Stage 2 complaint.

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 advertiser's trade association and/or Health Canada for their assessment of additional penalties. The PAAB sent 1 monitoring notice.

STAGE TWO DECISIONS

1. ADVERTISER: Oral Dent Pharma

COMPLAINANT: Experichem Labs

SUBJECT: Periplus Brochure

PRECLEARANCE: No

ALLEGATIONS: misleading claims

DECISION: Product has not been approved for use in Canada by health Canada. Therefore, complaint transferred to Health Canada.

OUTCOME: awaiting response from Health Canada.

For information or if you have comments:
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