January 2013

PAAB VIEWS

PAAB 300-1305 Pickering Parkway, Pickering, Ontario L1V 2P3
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INSIDE THIS ISSUE

"HAPPY NEW YEAR"

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.

NEW STAFF ADDITIONS

The PAAB has recently hired two new reviewers. Malikha Ladha joined us in November 2012. She is a licensed Pharmacist in Quebec and Ontario and has a Pharm. D degree from the University of Montreal. Vivien Fong is a licensed Pharmacist and Naturopathic Doctor. She has degrees in Music and Pharmacy from the University of Saskatchewan and a degree in Naturopathic Medicine in Toronto.

Implementation
July 1, 2013

"Come to a training session Montreal February 26 and Toronto February 28"

CODE REVISION

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.

The code is posted on the PAAB web-site in English and French.

There will be extensive client training sessions and activities:

1. We are in the process of completing and polishing our internal guidelines. They will be posted on the PAAB web-site.
2. Encouraging people who know the current code and apply it in their company to read the code and see the changes and determine how they apply it to their company needs
3. Jan-Feb 2013 - training PAAB staff in preparation for early review requests
4. We have hired Jon Gwillim to organize February 26 and 28 open events in Montreal and Toronto for all day intensive, interactive training designed for people who can train others within their own company. See our web-site for details. We have considerably reduced the fee from previous years.
5. In March we will have five webinar Q&A sessions of 1 to 2 hours prn
6. As of March 1 we can meet requests for in house company training with PAAB staff – 2 hour sessions at your office for a fee. Enquire.
7. We will publish articles in Canadian Marketing journals as requested/allowed.
8. Jon Gwillim is receiving questions to be answered by the Commissioner and put into reports leading up to the July 1 deadline.
9. We have put notices in the LinkedIn group, "The PAAB". It is no cost to you to join in on the fun.
10. Staff will answer specific code questions on the phone.
11. Watch our web-site www.paab.ca for more news.

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.

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.

Contact Commissioner Ray Chepesiuk for details and fee information 905-509-2275 x28.

NOTE TO CLIENTS RE: GENERIC PRODUCTS

The PAAB asked Health Canada for a position statement regarding generic pharmaceutical products. This is what we received from Health Canada:

"*First of all, we wish to bring to your attention the "It's Your Health (IYH)" article that Health Canada has published with respect to the safety and effectiveness of generic drugs. It is available at: http://www.hc-sc.gc.ca/hl-vs/iyh-vsv/med/med-gen-eng.php. This document clarifies that to prove that their products are safe and effective, generic drug manufacturers must demonstrate that the generic drug performs similarly to the brand name drug. This means that Health Canada requires that comparative bioavailability studies (i.e. bioequivalence studies) be conducted to measure the level of a medicinal ingredient in the blood of healthy human volunteers. The generic drug must show that it delivers the same amount of medicinal ingredient at the same rate as the brand name drug. As well, manufacturers also have to demonstrate that their non-medicinal ingredients are not altering the quality, safety and effectiveness of the drug. When these requirements are met, the generic drug is considered bioequivalent and consequently, this means that the product has met the same safety and efficacy standards as the brand name drug.*

The quality standards for brand name and generic drugs must also be the similar. The ingredients, manufacturing processes and facilities for all drugs must meet the federal guidelines for Good Manufacturing Practices (GMPs). As well, drug manufacturers must perform a series of tests, both during and after production, to show that every drug batch made meets the requirements for that product.

Therefore, in order to address some of your concerns, Health Canada confirms that generic drugs, when authorized for sale by Health Canada:

- *Are considered as safe and effective as brand name products;*
- *Are of the same quality as brand name products when the GMP requirements are met; and*
- *Works in the same way as brand name drugs in the body when the conditions of use and the dosage forms are the same.*

We trust this provides the necessary clarifications."

REVIEW ACTIVITY

During the period of January 1 to December 31, 2012, the total number of first review submissions was 7,042 files with 48 files going more than 10 days on first review. In 2011 the PAAB reviewed 6,901 new submissions. The median of turnaround for first review was 7 days. The reviewers averaged 2.1 days for turnaround on revision.

To address industry perception, 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.

The average number of total revisions per submission for a file was 2.2 in 2012. 14% of accepted files took more than 3 revisions to complete in 2012 versus 12% in 2011.

7,042 files is the highest one year volume in the 37 years history of the PAAB.

PAAB COMPLAINT REPORT

During the period of January 1 to December 31, 2012, the PAAB Commissioner processed 5 Stage 2 complaints. Two complaints were referred to health Canada in accordance with Health Canada policy regarding complaints including safety allegations.

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. In 2011 the PAAB sent 3 monitoring notices.

The 5 stage two complaints in 2012 was the lowest number for one year in 37 years.

STAGE TWO DECISIONS

1. ADVERTISER:

COMPLAINANT:

SUBJECT:

PRECLEARANCE:

ALLEGATIONS:

DECISION:

PENALTY:

OUTCOME:

2. ADVERTISER:

COMPLAINANT:

SUBJECT:

PRECLEARANCE:

ALLEGATIONS:

DECISION:

PENALTY:

OUTCOME:

For information or if you have comments:
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