Note from the Commissioner

Half the year has gone by and we continue to see a lot happening for the PAAB at the board and Operations levels.

The strategic plan was ratified at the AGM on April 21, 2017. The commissioner has developed an Operational plan, that looks into the future, based on that report.

Internally we have implemented a modern HR platform to improve our performance review system and enhance internal communications.

We have had a busy first half on the review side and it appears to be a record review volume for the first half of any year. We thank our clients for their continued support. On the complaints side, we have had five stage two decisions this year. Two are in stage three appeal.

As part of the new plan to improve communications, we have finalized a new digital, interactive format for the code and that was approved by the board on April 21, 2017, at the AGM.

Implementation will be January 1, 2018, and we are working on communications plan to inform our clients. A staff committee has been working with Innovasium to create and develop a new website that we continue to work on.

The ticketing/tagging system was implemented earlier this year and clients are starting to be

familiar with it and we look forward to analyzing the data.

We are deep into the preparation with Jon Gwillim of CreateHealth for the November training workshops to be held in Montreal and Toronto. Stay tuned as communications get unrolled. We hope to see you there.

We had the bilateral meeting with Health Canada on April 18, 2017, during which we exchanged information and discuss issues of mutual concern. When we get the minutes we will post them on our website. We also had a bilateral meeting with members of Health Canada regarding the advertising of self-care products as part of our attendance at the Health Canada consultation meeting on the modernization of self-care product regulations.

The PAAB staff has held up well through all this business, change and creativity. They are to be commended.

Sincerely,

Ray Chepesiuk

PAAB Commissioner

PAAB Stats

January 1 through June 30, 2017

- Number of submissions: 3930
- Time to first response: an average of 6.0 days. 4 files beyond day 10.
- Time to revision response: average 2 days

New PAAB Guidance Documents added to

the website

Since the previous newsletter, the following review tips document has been added to the PAAB website:

How to present support program names

When program names can be interpreted as a claim, benefit or status for the sponsor's product, the program… Read more

[links to]:

http://paab.ca/How_to_present_patient_support_program_names_-_July__17.pdf

Since the previous newsletter, the following review tips document has been updated on the PAAB website:

Study Presentations Involving Dose Titration (an application of s3.1)

[links to]:

http://paab.ca/Study_presentations_involving_dose_titration_(an_application_of_s_3_1)._July_2017.pdf

The update elaborates on the level of emphasis required for the disclosure in Case 1a.

If you'd like to know as soon as new documents are posted, follow us on Twitter @ThePAAB.

Code Change Update

You'll soon have access to the new digital and interactive format for the code. You'll recall from prior newsletters that it was approved by the board on April 21, 2017, at the AGM following broad stakeholder consultation. Implementation of this code will be January 1, 2018.

The Code Change Committee, a multi-stakeholder committee, improved on the existing code by:

- optimizing how content is organized
- adding definitions
- aligning language throughout the code

The most significant changes to the code relate to its format. For example, the new code enables users to perform keyword searches and to filter for all code provisions which are relevant to particular core principles. Although the language has been streamlined for clarity by

a professional writer, the regulatory provisions have not changed. As some code sections were moved, you'll note changes in the code numbers cited in PAAB correspondences following the January 1, 2018 implementation. A concordance table will be available to help you transition from the current code to the future code.

You can access a video preview of the code by visiting the following URL: https://recordings.join.me/6BVwgoMTlUqb7KlzGWKMAA

The code app will soon be available from our website for you to explore. Stay tuned for more information.

Complaint Report

There were no stage two rulings in the second quarter.

UPDATE

Subject – Stage Three Appeal of Ruling in Amgen Stage Two Complaint vs Merck Brenzys APS in Biotechnology Focus

An appeal hearing was held July 18, 2017. This is a verbatim report from the hearing.

"PAAB Appeal Amgen vs Merck Brenzys July 18, 2017

This Appeal Panel included Anne Tomalin, President, TPIreg Inc. (Chair); Lucie Dufour, Lawyer, Lucie Dufour Lawyer Inc; and Mike Cloutier, Founding Partner, Accelera Canada Inc. On July 18, 2017, the Panel heard arguments from Merck, Amgen and PAAB regarding an editorial that had appeared in Biotechnology Focus. Individuals representing Merck included: Cindy Belanger (UT Avocats), Anne Mayrand, Director, Legal & Compliance and Philippe Dussault, Director, Biosimilars and Loss of Exclusivity Brands. Individuals representing Amgen included: Emily Sherkey (Torys), Andrew Bernstein (Torys) and Ryan Lennox, Director and Senior Counsel for Amgen. Ray Chepesiuk, Commissioner of PAAB, presented on behalf of that organization. Patrick Massad and John Greiss were also in attendance from PAAB.

The issues considered by the Panel included the following:

- Does the journal piece under discussion meet the bar of "paid advertising

directed at Healthcare Professionals"?

- If so, does the journal piece meet the requirements of the PAAB Code?

In coming to its decision, the Panel was sensitive to the precedents that would be set in making its decision for the innovative pharmaceutical industry. The Panel was also sensitive to the spirit and intent of the Code, in its interpretation of the words used therein.

The Commissioner of PAAB determined that the journal piece was an Advertising Promotional System (APS), Health Canada also determined that the journal piece was "advertising" and Merck advised that they accepted Health Canada's decision that the journal piece was "advertising". Therefore, the Panel did not address the issue of whether the journal piece was advertising.

In determining whether the journal piece was an APS paid for by Merck and directed to Healthcare Professionals, the Panel determined that the editorial was directed to the audience of Biotechnology Focus, which includes the following Healthcare Professionals: practicing healthcare professionals involved in conducting clinical investigations, practicing healthcare professionals involved in making reimbursement decisions and practicing healthcare professionals involved in the biotechnology industry. The Panel struggled with whether the editorial was paid for by Merck, either directly or indirectly. In their final decision, the Panel concluded that the editorial was paid for directly and indirectly by Merck. Direct payments included the ads placed by Merck in the journal and indirect payment involved the emerging relationship that was developing between the company and Biotechnology Focus.

The Panel, therefore, determined that the editorial was paid for by Merck and directed towards Healthcare Professionals, among others. This APS required PAAB approval before use, as determined by PAAB and Amgen.

In coming to this decision, the Panel also decided to make the following recommendations to Industry, to PAAB, and to Biotechnology Focus.

Recommendations for Industry

- Interviews to the media should be conducted under SOPs. The SOPs should be developed in consideration of the PAAB code. Those conducting such

interviews should be clear in terms of the limits that should govern their comments for a specific product.

- Industry should review editorial pieces from the media to assure that rules required for advertising of Drugs in Canada are met.
- When the media use PAAB-approved material, industry should object to the use of this material unless it is used in its entirety as it was approved by PAAB. The "PAAB approval" should be removed from the use being done by the media.
- When complaints are raised regarding an APS such as the one under review, in this case, the Industry shall proactively modify the APS or require the third party to modify the APS. If the third party does not agree to the modification, there will be a record at the company of the directive requesting a modification.

Recommendations for the Media

- Editorials focused on one product should be avoided. More than one interview should be conducted, including individuals with varied points of view.
- Media should consider how an editorial piece will be considered by organizations at arm's length from the journal and shall keep in mind regulations and limitations related to drug advertising in Canada.

Recommendations for PAAB

- The requirement for an APS to be paid for by the company in the PAAB Code should be removed.
- The definition of healthcare professionals in the PAAB Code should be amended to expressly include those individuals involved in making decisions for reimbursement.
- The requirement for advertising to be intended to influence prescribing practices in the PAAB Code should be amended to expressly include also the intent to influence the dispensing practices of healthcare professionals."

Training and Events

Come join us for our 2017 National Workshop.

The event will be held in **Montreal** on **November 15th** and in **Toronto** on **November 17th**. In the last 2 years a total of 800 people from the industry have attended it. The event is an excellent opportunity to network and learn.

The curriculum will include discussion on how to leverage the full functionality of the 2018 change in code format in order to improve your understanding of the standards in the Code of Advertising Acceptance.

The key learning objectives of the event are as follows:

- Health Canada update with insight to the possible impact on HCP communications.
- Apply Fair Balance compliantly across your simple and complex advertising.
- Understand how to visually present information in a manner which adheres to the PAAB code.
- Learn how the code can guide the creation of compliant patient information.
- Exploration into digital campaigns across web platforms, formatting of emails, SEO and SEM.

Registration is now open.

You can view the **complete brochure** and learn about the **early bird registration** rates from the following site: **http://www.paabtraining.com/thank-you.html.**

The PAAB Code

To see the current edition of the PAAB Code, visit our website.

Our Mission

Vision: PAAB will be a world-class leader in supporting truthful advertising of health products.

Mission: To deliver pre-clearance review services that support trustworthy health product communications that comply with the Canadian regulatory framework

Values: Integrity, competency, credibility, independence, excellence, transparency

Social Media

- PAAB LinkedIn Group
- PAAB LinkedIn Page
- PAAB Twitter

Contact us

We're here to help you get to yes.

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