



PHARMACEUTICAL ADVERTISING ADVISORY
BOARD | APRIL 2018

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

Note from the Commissioner

The first quarter of 2018 has shown a record number of first quarter submissions to the PAAB, reflecting a healthy number of NOCs granted by Health Canada in 2017. New products continue to come to market. This has kept the staff busy. I am pleased to say the turnaround statistics have been very positive in that the time to review first submissions and revised submissions continues to be low. We have a great staff at the PAAB.

The Annual General Meeting is coming up in April and we are looking forward to the board reviewing two new code issues: the definition of advertising in the PAAB code and the use of Real World Experience data to support advertising claims. I note that the board has completed its governance review and we look forward to effective and efficient direction from the board. We had our annual bilateral meeting with Health Canada on April 4, 2018, and the major discussion topics raised were: the new legislation related to Natural Health Products, the new Cannabis legislation, and the new legislation related to vaping products. We had a chance to update Health Canada officials on PAAB stats and current activities.

We are near to receiving the results of our annual client survey which consists of feedback from about 120 client personnel. We learn from this feedback and we have demonstrated that

by making change to the Code based on client feedback.

As 2018 continues on, we look forward to serving our clients to help them achieve their ethical marketing efforts.

Sincerely,



Ray Chepesiuk
PAAB Commissioner

PAAB Stats

January 2018 through March 2018

- ✓ Number of submissions: 2196
- ✓ Time to first response: an Average of 5.4 days.
- ✓ Time to revision response: Average 1.9 days



New PAAB Guidance Documents added to the website in 2018

No new guidance documents were added to the website during this quarter.

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

New Code and Website Format

As a reminder, the new Code and Website formats are up and running. All PAAB letters will cite the PAAB code sections from the new code format. As some code sections were repositioned to improve the code flow, you may notice changes in some of the code sections referred to in our letters. This has no impact on what is (or is not) acceptable. You can directly access the PAAB Code App at the following URL: <http://code.paab.ca>. Alternatively, the code App may be accessed through our website at www.paab.ca. On the website, the code is accompanied by a letter describing how this innovation will benefit you. The letter also identifies which code sections have been repositioned. The letter can also be accessed at the following URL: http://www.paab.ca/resources/Letter_from_commissioner.pdf

You will notice that the format of the PAAB website has also been improved. While the new code format was designed to help you get more out of the PAAB code, the new website format was designed to help you get more out of all the other important information on the website. One of the key website features includes the ability to search and filter for documents on the website such as guidance documents and review tips. To help you keep up to date, you are now able to identify any newly posted documents as soon as you go to the resource page. They are listed at the top of the resource page accompanied by the icon “new”. This is just another step towards realizing our vision of being a world-class leader in supporting truthful advertising of health products.

Medical Cannabis Update

On April 4, 2018, we met with Health Canada officials from the Office of Medical Cannabis as part of the annual meeting with Health Canada. They shared the latest information with us that we Can share with you.

It is important to note that medical cannabis regulations were brought into effect in 2016 to allow Canadians reasonable access to a legal source of cannabis for medical purposes. As of March 29, 2018, 97 licenses have been issued for the production of cannabis for medical purposes. As of December 31, 2017, there were 269,502 clients registered with Licensed Producers.

Bill C-45 (The Cannabis Act) received final approval in the House of Commons on November

27, 2017 and they expect Senate approval on June 7, 2018. The provinces have asked for 8-12 weeks between Royal Assent and when the new laws come into force.

The Act would use federal criminal law power to create a strict framework to control and regulate the production, distribution, sale and possession of cannabis.

There will be no difference in advertising regulations for medical cannabis or recreational use cannabis. The promotion scope includes restrictions on all forms of communications including: printed publications, Internet publications, direct mail, signage, broadcast and mobile devices.

Prohibitions include: appealing to young persons, lifestyle, sponsorship, testimonials or endorsements, depiction of a celebrity, character or animals, false, misleading or deceptive, about a game, draw, lottery or contest that could induce anyone to increase cannabis consumption.

Promotion exceptions include:

1. Informational (e.g. cannabinoid content (%THC, CBD), species (indica, sativa)
2. Brand-preference promotion (e.g. logo, slogan, tradename)

These cannot be neither appealing to youth nor by associating it with a way of life.

There is a lot more to the story however, I have tried to give you a brief overview of the promotion requirements, which are very restrictive. Stay tuned.

FAQ about the PAAB Code Change

We've been asked multiple times whether Section 6.6 (vii) from the previous version of the code no longer applies (or whether it was deleted by an error during the code change). As a reminder, section 6.6(vii) had stated: "Disease information materials which make no mention of treatment by name, class, or category AND are not linked to healthcare product advertising in any way, are exempt from PAAB preclearance". This code copy was removed by the multi-stakeholder committee simply to streamline the code. The copy was considered redundant given the other provisions listed in that part of the code (i.e. this does not signify a change in the breadth of the scope of preclearance).

PAAB Complaint Report

4. ADVERTISER: Tribute (Aralez)

COMPLAINANT: Pediapharm

SUBJECT: C18-02 Tribute Blexten leave behind and Booth Panels

PRECLEARANCE: Yes

ALLEGATIONS:

1. S2.1, 2.4. *"As stated in our previous correspondence, the content of the Blexten promotional material is vague and does not reflect all the cautionary information from the Blexten product monograph that must be communicated to healthcare professionals. As a specific example, the proper administration of Blexten, as stated in the Health Canada approved product monograph, that "BLEXTEN TM once daily should be swallowed with water on an empty stomach to achieve optimal exposure to bilastine. The BLEXTEN TM tablet should be taken without food or grapefruit juice or other fruit juices, as these dietary compounds may decrease the effect of bilastine." This very important information needs to be clearly communicated to physicians so patients can be instructed on proper dosage and administration. In our opinion, the proper communication of dosage and administration of a new drug has always been a priority for the safety of the patient."*

2. S2.4, 2.10, 2.10.1: *"Blexten: A new treatment for seasonal allergic rhinitis and chronic spontaneous urticaria" - This claim implies that Blexten can be given to all patients with seasonal allergic rhinitis and chronic spontaneous urticaria. This does not reflect the limitations of the product monograph and the approved indications by Health Canada"*

3. *"A study was performed to assess the effects of BLEXTEN and bilastine 40 mg on real time driving performance. .. By stating that bilastine 40 mg was studied "in real time driving performance" before the indication and the appropriate dosage are stated, this can mislead healthcare professionals to believe that bilastine 40 m is a roved b Health Canada, which is not the case."*

4. *"Section on "Pharmacodynamic profile" The Pharmacodynamic section only*

emphasizes the positive features of Blexten and ignores the negative findings that should be included because of the significant impact on treatment such as:

Drug-Food Interactions

Plasma bilastine C_{max}, AUC_{0-t}, and AUC_{0-inf} values were approximately 33%, 17%, and 18% lower, respectively, for subjects receiving BLEXTEN™ following a high-fat breakfast compared to BLEXTEN™ administered under fasted conditions. Plasma bilastine C_{max}, AUC_{0-t}, and AUC_{0-inf} values were approximately 25%, 26%, and 25% lower, respectively, for subjects receiving BLEXTEN™ following a low-fat breakfast compared to bilastine administered under fasted conditions. The Phase 3 clinical trials were conducted under fasting conditions to ensure clinically appropriate exposure to bilastine.

Grapefruit Juice

Concomitant administration of BLEXTEN™ and grapefruit juice decreased bilastine bioavailability by approximately 30%. Concomitant administration of BLEXTEN™ with other fruit juices may also decrease bioavailability. The degree of bioavailability decrease may vary between producers and types of fruit juice. The mechanism for this interaction is an inhibition of OATPIA2, an uptake transporter for which bilastine is a substrate. Medicinal products that are substrates or inhibitors of OATPIA2, such as ritonavir or rifampicin, may likewise have the potential to decrease plasma concentrations of bilastine.

We also note that there is no mention of potential Drug-Drug Interactions, which can have a marked effect on bilastine plasma concentrations.”

DECISION:

1. I agree with the allegation from Tribute. For a Healthcare Professional the Administration section in the Product Monograph contains important information relevant to optimal use of the product. In the case of Blexten HCPs should be aware of the administration section prior to prescribing or recommending the product. The claim “One dose, once daily” brings emphasis to the dosing and that should be balanced by instructions for proper use of the product to get optimal results. This requires fair balance. That can be done by adding a footnote in close proximity to the dosing claim to provide adequate fair balance.
2. I do not agree with this allegation because the PM indication is clearly stated in the APS in reasonable proximity.
3. I do not agree with this allegation because the information is complete and

provided in a manner that does not mislead and is in accordance with the PAAB standard. The complainant has not provided proof of this being misleading.

4. I don't agree with Pediapharm because the presentation in the APS is consistent with current PAAB review practices if Tribute addresses allegation #1 about the proper administration.

OUTCOME:

Therefore, I find allegation #1 to be substantive and worthy of correction. This can be addressed in future APS. PAAB will not renew the current APS when they expire.

We encourage Tribute to address allegation #1 as soon as is possible to avoid the perception of misleading advertising. Both parties agreed with the ruling.



Training and Events

Are you making the most of the PAAB's innovative tagging system?

The tagging system was created to enable our clients to efficiently provide feedback and thus help us enhance the PAAB preclearance mechanism. There is a wide spectrum of standardized tags ranging from review issues such as perceived inconsistencies to perceived

opportunities for improving the code and/or guidance documents.

Once created, the tag remains on record and cannot be deleted by any PAAB staff. As per client request, **client tags are NOT visible to the reviewer.**

What's the value?

- Utilizing the tagging system empowers our clients to express their feedback and get it documented (exactly as expressed) directly into a single centralized record.
- It enables the PAAB management team to detect trends which can lead to the expedient implementation of improvements to our processes, procedures, and practices (e.g. training & development).
- It can assist in determining areas of focus during audits of the preclearance system.

eFiles Submission Form Enhancements

Coming soon!

The PAAB will be launching a new and improved Submission Form for use within the efile's platform as part of the PAAB preclearance review system.

Remember our Survey? Well, you asked, we listened, we did it!

We are pleased to provide a more user-friendly submission form, to include instructions on how to complete the necessary fields and a more innovative submission library, allowing clients to search and retrieve previously submitted documents with ease, within a secure APP platform.

Thank you for participating in the eFiles submission survey. Your feedback is vital and invaluable to PAAB's process improvement.

Keep an eye for more details to come in the very near future.

Annual National PAAB Workshop

The dates for the PAAB workshop have been set. Reserve the date on your calendars!! We plan on holding the Montreal event on November 20th and the Toronto event on November 22nd, 2018.

Stay tuned for information about the agenda and for information about registration.



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

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