English April 2019 Newsletter

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PHARMACEUTICAL ADVERTISING ADVISORY BOARD

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

A note from the Commissoner

The first quarter of 2019 was action packed. We got a lot done.

We analyzed the proposed RWE Code Change feedback received from 10 organizations (see below).

We modified the staff structure such that it now includes Senior Reviewer roles to support some of the initiatives we are taking on (many of which are discussed herein).

We started planning the 2019 national workshops. They will be held November 26th in Montreal and November 28th in Toronto. Save those dates!! The PAAB national workshop is a great opportunity to better understand the PAAB Code, meet PAAB staff, and network with peers from the industry.

The Canadian Animal Health Institute (CAHI) and PAAB have entered into a service agreement where PAAB will provide the Expert Opinion Assessment for Step #2 of the "CAHI CODE OF MARKETING PRACTICE" compliant resolution process.

Our first client advisory panel was a tremendous success. It resulted in Board Approval of the building of forum functionality on the PAAB website (see below). We'll be generating another panel in the upcoming weeks.

As 2019 continues to unfold, we look forward to implementing new initiatives that will support enduring continuous improvement in our processes, policies, and procedures. We are eager to help our clients meet their ethical marketing objectives.

Patrick Massad Acting PAAB Commissioner

PAAB Stats

January - March 2019

- Number of submissions: 1922
- Time to first response: Average of 5.4 days
- Time to revision response: Average 1.9 days



Real World Evidence Update

The stakeholder feedback period for the proposed RWE code / guidance change code ended January 31, 2019. Ten organizations provided feedback. These organizations largely applauded the PAAB for initiating a process intended to modernize its code and guidance vis-a-vis use of RWE in advertising. However, it's clear that from the feedback that industry would prefer a more permissive approach than that which was initially proposed by the committee. We've learned that Health Canada, CADTH and INESSS are currently collaborating on a framework intended to define Decision-Grade RWE and its role in Canada. You can learn more about this collaborative effort here: CLICK HERE.

Once sufficient information about this framework is available the expert committee which generated the proposed RWE Code / Guidance change will be reinstated. This committee will revise the proposed PAAB code / guidance to reflect, where appropriate, the stakeholder feedback on the prior draft version and insights from the Health Canada / CADTH / and INESSS framework.

All PAAB content converging into one source

PAAB generates a lot of content intended to support our clients in their day to day application of the PAAB code. Over the years, we've accumulated nearly one-thousand individual pieces of content. This includes:

- Guidance documents
- Tip documents
- Infographics
- Documented answers to questions
- Checklists
- Case studies

Some of this content is stored on paab.ca while other content is stored on other PAAB controlled websites (e.g. paabtraining.ca), on social platforms, and on partner / affiliate websites. This diversity in sources of information can create a disjointed search experience for our clients.

Soon, we'll be converging all PAAB generated content into the same source within paab.ca. This will empower our clients to access all PAAB content through a single search. We hope this will enhance customer efficiency, learning, and confidence.

PAAB will remain active in LinkedIn and Twitter, with content informing our social followers about new content added to paab.ca. Our posts will include direct links to support our follower's attempts to share these documents through the social platforms. We will also continue to work with affiliate / partner websites in any way that enriches the customer

PAAB Complaint Report

There were no stage 2 complaint rulings in the first quarter of 2019.



Training and Events

PAAB website is going social

We are in the process of enabling social functionality on our website. Each document on www.paab.ca will have its own comment feed. This will enable individuals to ask a question in the context of the particular document that triggered that question. When others read the document, they'll be able to see any questions and answers associated with it. Share functionality will make it easy for users to disseminate content to their collogues and ranking functionality will enable users to prioritize or filter search results by a community determined utility score (in addition to recency or document category).

This functionality will also provide an easy way for clients to post suggestions pertaining to

the code and guidance documents. This will complement the tagging system quite nicely. You'll use the tagging system to confidentially raise issues encountered during the review process while you'll use the social functionality to publicly suggest improvements to the code / guidance.

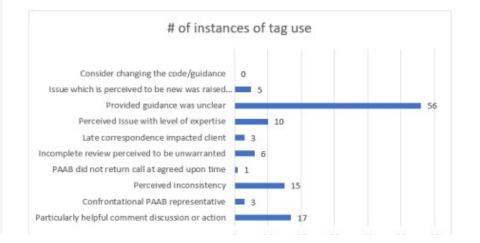
In addition to supporting transparency, this initiative will drive continuous improvement of the documents on our website, support client training efforts, and enhance overall level of engagement with our clients. You'll hear a lot more about this initiative soon. Stay tuned.

I'd like to thank the PAAB Website Social Functionality Committee for the insights they contributed. Participants included:

- Jennifer Carroll (Chair). PAAB.
- Juliana Aristizabal. Outpost379.
- Natalie Bourré. Marketing 4 Health.
- Margot Arntfield. Klick.
- Jaymie Blanchard. Novartis.
- Dorothy Czylyski. No Fixed Address.
- Richard Godin. Bristol-Myers Squibb.
- Jonathan Gwillim. CreateHealth.
- Patrick Massad. PAAB.

Client Tagging Results (for 2018)

The first graph below presents the total number of client generated tags in 2018 (prior to validation). The reader will note the use of language like "perceived". This is intended to indicate that the pre-validation data includes perceived issues that could eventually be validated in addition to perceived issues that could not be validated.



The following table isolates the specific instances that I was able to validate.

Issue	# of validated instances
Confrontational PAAB representative	1
Actual inconsistency	2
PAAB did not return call at agreed upon time	1
Late correspondence impacted client	1
Provided guidance was unclear	6

Qualitative analysis and actions taken:

One of the inconsistencies related to a claim which was previously approved in error. The ruling in the tagged submission was inconsistent with the prior ruling to avoid propagating the error. The other inconsistency related to a reviewer explanation which was inconsistent with the PAAB guidance documents (although the ruling in and of itself was accurate in this case).

The 6 validated instances in which PAAB could have been clearer related to revision requests which provided insufficient explanation of how the questioned copy contravenes the code. During a reviewer meeting, emphasis was placed on the importance of communicating how the questioned APS message exceeds the TMA, is inconsistent with the Canadian Consensus guidelines, or is inconsistent with the provided reference. Also, in response to this internal audit, fictious cases mirroring the unclear instances are being generated to enable the reviewer team to study the correspondence attributes that have resulted in documented clarity challenges.

Why could so few tags be validated?

The most common reason that tags could not be validated is the absence of tag comments explaining what was inconsistent or unclear about a review. As the context conveyed in the ticket comments is critical to our understanding of what is perceived to have gone wrong during the review and what PAAB can do better, we are making substantial changes to the tagging system. These improvements will enable clients to complete the tag (with comments) in mere seconds. Stay tuned for more on this.

Why does any of this matter?

The critical ingredients for a "high quality" review include timeliness, accuracy, consistency, clarity, and a valid basis for rulings. A review's quality is only as high as the weakest of these critical properties.

The tagging system enables a more wholesome view of "review quality" by empowering us to assess review accuracy, consistency, and clarity through the following tags:

- Accuracy:
 - "The reviewer raised new comments late in review"
 - "There are perceived issues with reviewer expertise"
- Consistency:
 - "Ruling was perceived to be inconsistent with code or guidance"
 - "Ruling was perceived to be inconsistent with other brands"
 - "Ruling was perceived to be inconsistent with prior rulings for the <u>same</u> <u>brand</u>"
- Clarity
 - "the requested revision was unclear even following a clarification phone call"

Note that timeliness is mostly quantified through our established metrics of time to first review and revision turnaround time. Also note that the social forum functionality described above will support continued validity of the documentation upon which rulings are based.

A client advisory committee will soon be generated to review these and other tags. If you'd like to participate on this committee, please reach out to me at patrickm@paab.ca

You spoke. We are taking action.

PAAB did client research (by survey) at the beginning of this year to measure performance against our goals and to provide insights on how to better meet industry needs. Here are highlights from the report:

Gist of statement	Avg score 1 = strongly disagree, 10 = strongly agree
Reviewers are available for questions/discussion	7.0
Reviewers assists with finding solutions	5.7
Reviews are consistent	5.1
First review is complete and thorough	6.3
I am aware of tagging system	5.2
PAAB is a model organization for independent review agencies	6.6
I value the PAAB as a source of knowledge and support for	6.6

If you'd like to see the complete report, CLICK HERE.

The results indicate that there continues to be opportunity for improvement. The initiatives discussed throughout this newsletter are intended to drive and sustain that improvement. The ongoing improvements in the tagging system should increase utilization of this important quality assurance mechanism. The tagging system is of great importance as it enables us to prioritize development / training activities based on trends. Also, being able to collect and analyze all instances which triggered a particular type of tag is extremely helpful as it enables us to identify specifically what we can do better. This is why we are investing in improving the tagging system.

Just as the tagging system will anonymously sustain continuous improvement in how the PAAB team helps you, the forum functionality on our website will sustain continuous improvement in our guidance documents.

PAAB Staff Update

Estelle Parkin retired in the first quarter of 2019 after 23 years at PAAB. PAAB Reviewers Chris Seto and Karen Rizwan also left the PAAB to pursue other opportunities. We wish Estelle, Chris, and Karen all the best and we thank them for the many ways they've contributed to PAAB's success over the years and decades. Ray Chepesiuk's retirement was featured in the prior Newsletter.

We welcomed two new members to the PAAB family in the 1st quarter of 2019:

- Chantal Gauthier joined PAAB's Administrative team in January of this year. Chantal has worked in various office administrative roles, including the financial and healthcare sector. Chantal is fully bilingual, loves to spend time with her children, including her furry ones.
- Erika Majdalani joined the Reviewer team. She is a pharmacy graduate from University of Toronto. Aside from her clinical background, she had a great interest in linguistics throughout university and has acquired fluency in 4 languages.



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

Contact us

- PAAB LinkedIn Group
- PAAB LinkedIn Page
- PAAB Twitter

We're here to help you get to yes. 300-1305 Pickering Parkway, Pickering, Ontario L1V 3P2, Canada Phone: +1 (905) 509-2275 Send email to info@paab.ca

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