July 2014

PAAB VIEWS

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INSIDE THIS ISSUE

"Oh, the summer night, Has a smile of light, And she sits on a sapphire throne."

- Bryan Procter

Year 2014 marks the 38th 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 for the benefit of all stakeholders.

VISION: Trusted healthcare product communication that promotes optimal health.

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

CODE BOOKS AND APP

You can get copies of the July 1, 2013 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 May and June focus groups to help us improve the PAAB.

GOVERNANCE REVIEW

The PAAB commissioned consultant John Dinner to conduct a review of PAAB board governance and report to the current board of directors. The directors received the report at the Annual general Meeting of April 25, 2014 and subsequently struck a committee to review, prioritize and recommend the suggestions presented in the report prior to the next board meeting in November 2014.

The mandate of the Task Force is to:

1. Review the governance review recommendations in detail with a view to ensuring common understanding as to their rationale, relevance and applicability;

2. Prioritize those recommendations the Task Force deems to be most important to the good governance of PAAB going forward, taking into consideration the input of other Board members;

3. As necessary, further define the outcomes the prioritized recommendations are intended to achieve to ensure clarity;

4. Develop a project charter to define the scope, approach, timeline and guide for implementing the prioritized recommendations for consideration and approval by the Board of Directors;

5. Develop and provide a rationale for the Board's consideration as to why certain recommendations are not part of the proposed implementation plan;

6. Serve as project sponsor, giving active oversight and guidance to the implementation of selected recommendations on behalf of the Board of Directors.

<u>Accountability and Reporting</u>

The Task Force is accountable to the Board of Directors and will report on the status of its work as appropriate or, at the very least, at each meeting of the Board.

PAAB WORKSHOPS

The PAAB will present an introduction to the PAAB Code workshop in the Fall 2014. November 4, 2014 in Montreal and November 6 in Toronto. We have developed a new format that will see PAAB Basic 101 didactic training for newbies in the morning session and a more advanced case study format in the afternoon session. You can sign up for one or the other or both. More info in The PAAB Linkedin group and on the PAAB web-site www.paab.ca

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PAAB SPEAKS

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

In May, Commissioner Chepesiuk and Deputy Commissioner Massad spoke on May 26, 2014 at the CreateHealth conference "*Create Value Added Service for Physicians, Patients and Payers*". Patrick Massad spoke at the EyeforPharma Patient Centricity 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 Deputy Commissioner Patrick Massad for details and fee information 905-509-2275.

REVIEW ACTIVITY

During the period of April 1 to June 30, 2014, the total number of first review submissions was 1,714 files with 20 files going more than 10 days on first review. In the same quarter 2013 the PAAB reviewed 1,958 new submissions. YTD total is 3,570 compared to 3,724 in 2013.

"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.

PAAB COMPLAINT REPORT

During the period of April 1 to June 30, 2014, 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 2 monitoring notices.

STAGE TWO DECISIONS

1. ADVERTISER: Bayer

COMPLAINANT: Boehringer Ingelheim

SUBJECT: Xarelto Detail Aid

PRECLEARANCE: Yes

ALLEGATIONS: 1. The visual layout of the dosing recommendations misleads the reader to believing that the primary dosing consideration for all of the NOACs is estimated creatinine clearance, when this is not reflected in the currently approved product monographs.

2. The primary consideration for dabigatran dose selection is based on the age of the patient. For most patients under 80 yrs, 150 mg BID is the recommended dose, with considerat ion of 110 mg BID for patients with increased risk of bleeding. For patients over 80 yrs,110 mg BID is the recommended dose. A more accurate way to illustrate this in alignment with our product monograph would be as follows (diagram shown).

3. As previously described,the manner in which the dosing selection algorithms have been displayed in the APS illustration implies that additional considerations are needed when determining the dosing for dabigatran compared to rivaroxaban. This illustration unnecessarily complicates the process and intentionally misleads the physician.

DECISION: The Bayer APS appears to be supported by the respective Product Monographs and the 2012 CCS guidelines. BOE may perceive a market disadvantage because the content of the two products differ significantly. That should be addressed with Health Canada. I see little merit in the Boehringer Ingelheim objection to the approved presentation. The approval appears to be in line with the usual PAAB policy for comparative drug advertising. BOE should be more aware of the limitations of the Pradaxa PM and apply it to Pradaxa advertising. I do not agree with the alleged violations.

OUTCOME: Decision Accepted.

PENALTY: $500 registration fee assessed to Boehringer Ingelheim.

For information or if you have comments:
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