



Pharmaceutical Advertising Advisory Board

Working together for an even stronger future

PAAB 2013-2016 Strategic Plan

APPROVED by The Directors November 15, 2013

Strategic Framework 2013-2016

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Exhibit 1
Our 3-Year Vision for an even Stronger Future

Exhibit 2
The key issues we face and that need to be addressed in our plans.

1. Introduction

Successful organizations recognize and celebrate their past achievements while also striving to innovate based on a view of future strength and success. We are proud of the PAAB's 37-year history and of the important service we have provided to our stakeholders. Over the next three years, we seek to further strengthen the organization *by engaging stakeholders in a role and mandate review to reenergize their commitment to the PAAB's role and purpose; by updating, as necessary, and clearly communicating the mechanisms we use to assure stakeholders of consistency in the application of the Code, and by enhancing stakeholder value through communication and training.*

Our clarity of focus, articulated in this plan, is the result of focused dialogue with our Board of Directors and senior managers in April 2013. Successful implementation of the strategic goals outlined in this plan will serve to strengthen PAAB and the benefits we provide to stakeholders within a changing pharmaceutical and health care industry.

As the environment in which we operate becomes increasingly complex, we face a variety of challenges – both general and specific. The challenges that have inspired the strategic focus outlined in this plan include:

- ❑ A changing regulatory environment. There is an increasing expectation to be more transparent. Physicians and pharmaceutical companies have to explain themselves. Consumer trust may have weakened.
- ❑ A changing health care and pharmaceutical landscape including an increase in demand for patient information and intensified pressure on Rx&D to produce real world evidence.
- ❑ Furthermore, Canadian companies are experiencing increased pressure for compliance in response to complaints and corruption in the US.
- ❑ Consumer trust in Canada may have weakened as a result.
- ❑ Increase in available technology and increased expectations as a result. PAAB will need to manage the implications of a rapidly evolving e-environment.
- ❑ More use of controlled advertising.
- ❑ Physicians have become more informed consumers of evidence-based advertising and most simply assume pre-clearance by some organization. PAAB? Health Canada? Other?
- ❑ Indeed, we face emerging competition from other groups and organizations for the pre-clearance of prescription drugs.
- ❑ The Code, while recently updated, needs to remain nimble in order to react to a rapidly evolving environment. For example, personalized medicine is on the horizon and biologics, rare disease medications etc. already challenge our pre-clearance protocols.
- ❑ PAAB's role within the industry must be clear to all. PAAB must secure stakeholder support and confidence.

We look to the future with optimism. Together we are prepared to work hard and do what is necessary to secure a strong and proud future for the PAAB and for our stakeholders.

2. An updated Mission Statement

Our mission statement is a declaration of our core purpose. PAAB's mandate is to "serve as an independent review agency with a primary role to ensure that healthcare product communication for prescription, non-prescription, biological and natural health products is accurate, balanced and evidence-based and reflects current and best-practice." (Code of Advertising Acceptance, 2009)

The leadership team sees no reason to change this description of PAAB's fundamental mandate or purpose, though does suggest a slight modification to the wording of our Mission statement to clarify the intent of our work.

Accordingly, we present the following updated Mission statement. We believe that this revised statement fully captures the core purpose of the PAAB and our intended impact.

"PAAB's mission is to provide a preclearance review that fosters trustworthy healthcare communications within a regulatory framework for the benefit of all stakeholders."

3. Our Vision guides our path forward

Within the context of our mandate, we have highlighted a vision that speaks to the intended impact of the work we do. Our challenge over the next three years will be to extend our reach within our mandate. For example, over this period interpretation of this vision may include medical devices associated with prescription drug use.

Evidence-based healthcare product communication that promotes optimal health.

We recognize this Vision as more than a simple statement of goal: Rather, it will continue to define and inspire decision-making in the years ahead.

4. Our commitment to core values anchors our focus

Over the years, PAAB has evolved to meet changing needs. At every decision-point, our flexibility has been grounded in our fundamental commitment to core values. This unwavering commitment continues to inform our current focus.



It is important to note that no one of these values takes priority over the other. Rather, they are inextricably intertwined, our ability to uphold one being very much dependent on success in upholding each of the others.

5. Strategic Focus 2013-2016

Any organization's success is typically proportional to its ability to focus. Accordingly, in this plan we recommend seven strategic goals within three key priorities consistent with the conclusions highlighted in Exhibits A and B attached.

Our seven strategic goals have been organized within three key priorities. To:

- A. *Engage stakeholders in a role and mandate review to ensure that the work that we do is well understood, accepted and endorsed. Furthermore, ensure that we have strong and effective governance arrangements to support delivery of this mandate.*
- B. *Update, as necessary, and clearly communicate the mechanisms we use to assure stakeholders of consistency in the application of the Code, and to*
- C. *Enhance stakeholder value through a variety of mechanisms including enhanced communication and targeted specialized education programs.*

The Commissioner and his staff team will develop a detailed plan to support the implementation of the goals within each priority. He will report progress in efforts to achieve these goals at each Board meeting. Furthermore, an annual review will be completed and additional goals developed as these first goals are achieved. Thus through the three-year life of this plan we will continue to set goals to advance our efforts to achieve our Vision for an even stronger and more effective PAAB.

The additional detail highlighted in our planning session is highlighted below:

Engage stakeholders in a role and mandate review to ensure that the work that we do is well understood, accepted and endorsed. Furthermore, ensure that we have strong and effective governance arrangements to support delivery of this mandate

Our strategic goals within this commitment

1. Undertake an independent review of PAAB's governance structure and mandate to address challenges of conflict of interest and to seek opportunities to extend our reach within our approved mandate (e.g. product monographs? Medical devices?) This review should also determine which governance structure will best support PAAB to make strategic decisions in future. (Policy Governance? A hybrid model? Etc.)
2. Undertake governance training for all directors.
3. Advocate for regulatory clarity and movement towards funding models that reduce conflict of interest. Seek a requirement by Health Canada that all healthcare products be pre-cleared.
4. Formalize and enhance the consultative and advisory role of the organization

Action steps recommended in our planning session:

- Commit funds to this initiative
- Establish a start and end date for the project
- Seek support from a third party approved by the Board
- Scope of review to include a definition of "who are PAAB's stakeholders?"
- Ask Alain Musende as our Health Canada contact to support this initiative.

Update, as necessary, and clearly communicate the mechanisms we use to assure stakeholders of consistency in the application of the Code

Our strategic goals within this commitment

5. We need a plan to address the perception of review inconsistency. Commissioner to form a committee consisting of one member of each of the four trade association members of PAAB. Committee findings will be posted on the PAAB web-site.
6. Perform a gap analysis on the code on an annual basis with a report presented back to the Board.

Action steps recommended in our planning session:

- Make sure that PAAB understands what are the common themes in inconsistencies that are identified. Develop a plan to address these.
- Seek granular data not just aggregated.
- Consider how the results of a review are communicated
- Form a Code Committee of the Board with a mandate to create a process for the review.

The detail that inspired this focus is attached as Exhibit 2.

6. Moving forward

Our success in the past, and the clarity of focus that is suggested here will be the foundation on which we will build a strong future in the years ahead. We are confident that success in addressing these goals will result in our becoming an even more effective preclearance agency. We recognize that we must not be complacent or resistant to change. PAAB must adapt in order to thrive and remain acceptable to stakeholders in the years ahead.

Exhibit 1 - Our 3-Year Vision for an even stronger future

Who we are and what we do				How we do it					Impact
Agency of choice for all drug advertising/communication				Flexibility in a changing environment, considering the patent cliff and the need for objectivity and adaptability while remaining consistent and unbiased.					
Excellence in providing expertise: reduces time and cost of preclearance to industry. Industry sees us as a partner.	Regular Code updates that react rapidly to a changing environment	Advocacy with Health Canada for improvement	PAAB review of consumer Rx information	Excellence in Governance	Enhanced communication and collaboration with stakeholders and continued efforts at transparency	Targeted specialized education	Movement towards funding models that minimize COI		Strong relationships with all PAAB stakeholders
Agency that brings value to advertising and communication.	Consistency and fairness in Code <u>interpretation</u>	Outreach: Seek to expand outreach effort to include health care practitioners and the public. Include HC in our efforts to engage HCP's.		Expand Board e-expertise	PAAB to make their procedures and approach and decisions more transparent to stakeholders. And increase outreach to improve cost to industry.	Certification program			Improved perception of independence
Broaden and clarify consultative role of PAAB	Increase and expand PAAB's scope: DTC, pet, Devices etc.	Regulatory advertising, consultation for non-preclearance.							

PAAB continually demonstrates <u>value</u> to all stakeholders	Explore expansion (US? EU?)	Regulations that provide clarity and mitigate conflict of interest							
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Exhibit 2 – The key issues we face and that need to be addressed in our plans.

We need to ...

<i>Engage stakeholders in a role and mandate review to update commitment to the PAAB's role and purpose</i>			<i>Update, as necessary, and clearly communicate the mechanisms we use to assure stakeholders of consistency in the application of the Code</i>		<i>Enhance stakeholder value</i>	
We need to undertake an independent Governance review	Advocate for regulatory clarity and movement towards funding models that reduce conflict of interest.	Formalize and enhance the consultative/advisory role of the organization	We need a plan to address the perception of review inconsistency	Perform an annual gap analysis on the Code and report back to the Board	Improve listening and communication with Stakeholders	We need to continue to educate and train internally and externally
Review Governance to avoid, mitigate perceived conflict of interest	Seek Health Canada policy definition to ensure that Industry adheres to section 9		<p>Action recommended:</p> <p>7. Make sure that PAAB understands what are the common themes in inconsistencies that are identified. Develop a plan to address these.</p> <p>8. Seek granular data not just aggregated.</p>	<p>Recommended action:</p> <p>Form a Code Committee of the Board with a mandate to create a process for the review.</p>	Increase the value of PAAB to our stakeholders	We need to modify and segment our training and outreach activities to lead to more targeted initiatives.

			9. Consider how the results of a review are communicated			
Need to review our Board structure	Must ask Health Canada to require that all healthcare products be pre-cleared by AN agency.				Transparency for stakeholders	Action recommended: Look at the suite of training initiatives and segments and consider how best to proceed.
<p>Action recommended:</p> <ul style="list-style-type: none"> • Commit funds to this initiative • Establish a start and end date for the project • Seek support from a third party approved by the Board • Scope of review to include a definition of “who are PAAB’s stakeholders” • Ask Alain Musende as our Health Canada contact to increase their attention to this. 					Action recommended: Have a group get together regularly to discuss this issue. Consider an annual survey and developing a PR plan with clear objectives.	