

Pharmaceutical Advertising Advisory Board

Strategic Plan

2017-2020

20 January, 2017

Message from the Commissioner

PAAB has fulfilled a critical need since it was created in 1976. PAAB was formed to fill a gap that provincial health ministers saw in the early 1970s, in the face of increasing complaints about drug advertising.

From the beginning, PAABs preclearance review service focused on pharmaceutical manufacturers. Since then, our business has evolved to keep pace with changes in how pharmaceutical information is shared with healthcare providers. In 1977, we did our first pre-clearance reviews for journal ads, and in 1978 we began reviewing direct mail, audio programs, and service-oriented products like desk calendars and

prescriptions pads. In 1988, we started reviewing detail material and digital material. Through the 1990s, we moved into veterinary drug advertising, and started providing opinions on Direct-to-Consumer advertising. Then, in 2003, we began to review patient materials.

Our operations have evolved as well. The PAAB Code of Advertising Acceptance has been revised seven times since it was first developed in 1978, including the last revision in 2013, which introduced major changes to address issues of evidence and fair balance, as well as digital advertising. In 2007, we introduced E-Files, which dramatically improved the efficiency of our processes.

All of this matters today, because it demonstrates our ability to evolve to meet changing needs. It shows that we are capable of being a nimble, responsive organization that is attuned to what's happening in the world around us. That world is changing faster than ever, but we have a strong foundation to build on.

I have been privileged to be a part of PAAB since 1985. I am proud of how we've grown and everything we have accomplished. I am also confident that, looking ahead at the next 40 years, PAAB has a significant contribution to make, and that we are unique in our ability to provide vital services that support industry, regulators, healthcare professionals and the patients that they treat. This Strategic Plan is the next step in that direction, and it is my pleasure to share it with you.

Ray Chepesiuk, Commissioner



Executive Summary

Goal 1: Awareness

PAAB is recognized as a valuable source of knowledge and support for trustworthy health product communications

Objective 1.1 Industry stakeholders are aware of PAAB's relevance in helping companies meet Canadian regulatory requirements

Objective 1.2 Healthcare professionals are aware of the role PAAB plays in pre-clearing advertisements

Goal 2: Training

PAAB is recognized as the industry-leading provider of training to support industry's success in credible advertising

Objective 2.1 Pharmaceutical marketing professionals value the Code as a tool that helps them meet their regulatory obligations

Objective 2.2 Companies have the technical capacity and skills to support their success in credible advertising

Goal 3: Innovate

PAAB innovates to meet the needs of healthcare professionals and consumers who rely on the materials pre-cleared by PAAB

Objective 3.1 PAAB is attuned to what healthcare professionals need from pharmaceutical advertising

Objective 3.2 PAAB is well-informed about industry and regulatory developments, and has the competencies needed to review emerging products

Goal 4: Operational Excellence

PAAB is recognized as a model organization for independent review agencies operating in a regulatory environment

Objective 4.1 PAAB has modern tools to support excellence in service delivery

Objective 4.2 PAAB demonstrates continuous improvement in how it manages its business

Introduction

The Pharmaceutical Advertising Advisory Board (PAAB) is an independent review agency that advises industry on compliance with Code of Advertising Acceptance. PAAB developed the Code as a tool to help industry meet the legislative and regulatory requirements for advertising established by Health Canada under the *Food and Drugs Act*.

The year 2016 was PAAB's 40th anniversary—a perfect occasion to pause and reflect, and think carefully about our future. This Strategic Plan for 2017–2020 recognizes that PAAB's planning approach needs to evolve with the environment around us. Building on what we set out to achieve in our 2013–2016 Strategic Plan, PAAB remains committed to the highest standards of service delivery and to adopting modern governance approaches. As we look ahead, we have also taken a broader view of the world we operate in. We have reflected thoughtfully on how we can leverage PAAB's greatest strengths, and we worked diligently to identify the trends that impact what we do, both on a day-to-day basis and in the long-term.

This Strategic Plan is the product of significant research and discussion among PAAB staff, the Board of Directors, and key external stakeholders who keenly understand the forces that shape the global pharmaceutical advertising landscape and Canada's place within it. It represents the collective wisdom of diverse professionals with unique points of view, but who share a common interest in making sure that pharmaceutical manufacturers are well equipped to meet Canadian regulatory requirements that were designed to ensure that health product communications for healthcare professionals meet the highest standards.

As a voluntary, self-financed organization, PAAB operates in a challenging environment. When PAAB first started operating in 1976, we reviewed approximately 400 submissions per year. In 2014, PAAB staff reviewed more than 7000 files. Submissions have been made by almost 100 different manufacturers, across 25 therapeutic areas. PAAB now serves approximately 150 agencies that submit advertising on behalf of manufacturers. These are more than just numbers—these figures demonstrate that we provide a valuable service in an industry that continues to grow. This Strategic Plan recognizes that reality, and anticipates the many other new, exciting developments that we hope our next 40 years will bring.

Our Vision

To honour our 40th anniversary in 2016, PAAB renewed its sense of purpose by celebrating our experience, and setting a new bar for ourselves that recognizes just how much we have to offer in our growing field of expertise.

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

Our Mission

PAAB's day-to-day work brings real value to all of our stakeholders. Our mission will keep us focused on activities that meet their needs, in service of the vision that we aspire to achieve.

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

Our Values

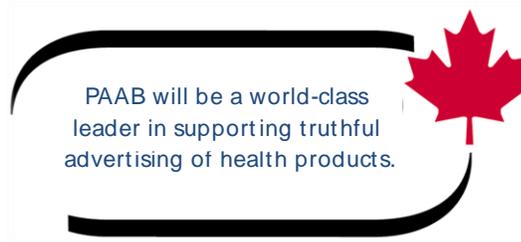
PAAB's values guide everything we do, every day. While internal and external forces may cause us to adjust our priorities or the tools we use, our values reflect the most basic approach we take in all of work, no matter what that work might be. We are proud to reaffirm the following values:

**Integrity
Competency
Credibility
Independence
Excellence
Transparency**

Against this backdrop, PAAB has identified four strategic goal areas for 2017–2020: **Awareness, Training, Innovation, and Excellence.**

Pharmaceutical Advertising Advisory Board Strategic Framework

VISION



MISSION

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

Our Strategic Goals

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Objectives:

PAAB has modern tools to support excellence in service delivery

PAAB demonstrates continuous improvement in how it manages its business

Our Values

Integrity
Independence

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Goal 1: Awareness

PAAB is recognized as a valuable source of knowledge and support for trustworthy health product communications

For 40 years, PAAB has played a critical role in pharmaceutical advertising by providing a voluntary pre-clearance review process for industry that supports trustworthy health product communications. While PAAB's core function has remained constant, the operating environment has changed considerably.

Interviews with stakeholders during the development of this strategic plan revealed consensus that PAAB's work remains as relevant as ever, in an era where consumers are seeking more information and governments expect greater accountability. However, we can more effectively communicate how we add value in today's ever-changing environment.

In a voluntary system, it is essential for industry to recognize the value proposition that PAAB offers, and for other stakeholders to understand PAAB's role and have confidence that our services benefit all Canadians. Demonstrating PAAB's ongoing relevance underpins many other activities in this Strategic Plan.

Objective 1.1: Industry stakeholders are aware of PAAB's relevance in helping companies meet Canadian regulatory requirements

As an independent review agency, PAAB has a long track record of success in delivering pre-clearance services that help companies demonstrate compliance with Canadian regulatory requirements.

Data demonstrates that complaints received by Health Canada about pharmaceutical advertising have consistently been related to material that was not pre-cleared by PAAB. Having advertisements pre-cleared through PAAB's review process can significantly reduce the risk that companies will face complaints and the associated penalties that can be levied by Health Canada.

PAAB's reviewers are highly trained, and the staff retention rate is high. This level of expertise, combined with an efficient e-file system, means that PAAB's average first review time is just seven business days. Communicating this value—and PAAB's relevance in fostering an efficient voluntary system—will help ensure that we continue to be seen as a vital service provider.

Tactics: Develop a comprehensive communications strategy to share key messages with pharmaceutical executives.

Objective 1.2: Healthcare professionals value the role PAAB plays in pre-clearing advertisements

The regulatory environment for health products is complex. Not all healthcare providers are aware of the rules that govern advertising, and some stakeholders, including many physicians and pharmacists, mistakenly believe that the government approves all advertisements.

While Health Canada has the authority to do this directly, PAAB's very existence came about because government leaders of the day wanted to adopt a different model. PAAB's success as an independent agency in filling the need for pre-clearance services has allowed Health Canada to focus its regulatory efforts in other areas. However, the system is still voluntary for industry.

If there was greater awareness among health care professionals of the key role PAAB plays in supporting trustworthy advertising, they would recognize the PAAB logo—something companies may only add to advertisements that have successfully pre-cleared—as a signal that the information in the advertisement is accurate, balanced, evidence-based, and reflects current best practices. In turn, companies would have a greater incentive to leverage the PAAB process to demonstrate their credibility. This would also allow PAAB to enhance its position as a leader in supporting trustworthy health product communications.

Tactics: Develop a comprehensive communications strategy to inform health care professionals about PAAB's role.

“We want to reach a point where health care professionals and consumers insist that PAAB be involved.” — PAAB Strategy Development Session, November 2016

Goal 2: Training

PAAB is recognized as the industry-leading provider of training to support industry's success in credible advertising

The high quality of PAAB's training for pharmaceutical companies is one of our biggest success stories. Demand for workshops remains strong, even among participants who have attended past sessions, and interest continues to increase for online training modules that

cover specific topics in more depth. More than 400 people attended in-person PAAB training sessions in 2016 alone.

Building on this success will strengthen PAAB's role as a leader in supporting trustworthy health product communications that comply with the Canadian regulatory framework.

Objective 2.1: Pharmaceutical marketing professionals value the Code as a tool that helps them meet their regulatory obligations

PAAB's workshops on the Code are well attended by pharmaceutical manufacturers, with the majority of attendees representing their company's government or regulatory affairs departments. However, discussions with stakeholders revealed that these participants are the ones most likely to recognize the value of the PAAB pre-clearance process. In some companies though, the challenge is to persuade marketing teams that the investment is worth it—because the evidence shows that it is.

Part of the challenge is a perception by some industry stakeholders of inconsistency among PAAB reviewers—an issue that was carefully examined in an audit that PAAB undertook in response to industry concerns. Although the audit did not identify any concerns with the review process, we see a significant opportunity to improve our outreach to industry, to help increase understanding about acceptable claims in advertising, and why certain language might be acceptable in one instance but not another.

Additional effort to recruit more marketing and advertising professionals to PAAB's training would enhance our ability to effectively advise industry on the Code, and communicate the value of the Code as a compliance tool for industry.

Tactics: Increase training opportunities to include sessions and tools that are tailored to meet specific needs.

Objective 2.2: Companies have the technical capacity and skills to support their success in credible advertising

The pharmaceutical industry continues to evolve, which can cause tension in the pre-clearance review process. New players are entering the market all the time, including smaller firms that have little experience navigating the regulatory system. At the same time, existing companies are exploring new product areas like biologics where the knowledge base is not yet well established. This can create challenges for companies, particularly when their learning happens in real-time as they're seeking pre-clearance approval. PAAB can respond to these pressures by developing additional guidance tools to complement formal training, and increase the ability of companies to present high-quality submissions.

For example, through its partnership with the Pharmaceutical Marketing Club of Quebec, PAAB shares information through the AskPAAB online portal. This web-based system allows marketers to get prompt feedback on questions that are relevant to current or future

submissions, and to search the database of answers to questions that other people have asked. Since its inception in 2006, the database has become a valuable, but underused resource.

Better promoting AskPAAB, and looking for similar opportunities for informal dialogue between advertisers and PAAB reviewers, will help improve industry's capacity to make high-quality submissions, while allowing us to maintain high service standards.

Tactics: Leverage informal opportunities such as "AskPAAB" to complement formal training.

"We need to reverse things, so that instead of asking, 'Why submit to PAAB?' the universal response from companies is, 'We have to go to PAAB to make sure we get it right.'" — PAAB Strategy Development Session, November 2016

Goal 3: Innovate

PAAB innovates to meet the needs of healthcare professionals and consumers who rely on the materials pre-cleared by PAAB

PAAB's long-term relevance is directly connected to our ability to forecast trends that affect all of its stakeholders. By making innovation a core goal of our Strategic Plan, we aim to position ourselves as a thought leader that not only adapts to change, but that helps lead it.

Making strategic decisions will require dedicated resources to stay abreast of what's happening across the pharmaceutical and advertising industries, both in Canada and abroad; actively engaging with relevant regulatory-focused organizations to identify and share best practices; and fostering dialogue between diverse stakeholders to ensure that our services are effectively fulfilling their needs.

As a starting point, the Environmental Forces and Trends document prepared as background for this Strategic Plan identified several key areas that, over time, may require varying degrees of our attention.

Objective 3.1: PAAB is attuned to what healthcare professionals need from pharmaceutical advertisements

New information is being published regularly, and digital information about emerging products is increasingly available to people who search for it. There is growing concern among all stakeholders that if credible information isn't provided in a timely way, healthcare professionals—and the consumers they serve—will simply find whatever information they can, wherever they can, without any way of being able to assess its truthfulness.

Credible advertising of pharmaceutical products is one way to share accurate information about new products with healthcare professionals. In today's healthcare environment, physicians' time is precious. As one of the primary audiences for advertising materials reviewed by PAAB, physicians will have their own views on what kind of information they need to make decisions that support their patients' health. By reaching out to physicians to ask what they need, PAAB can ensure that its work remains relevant and focused, and that credible advertising continues to be a viable tool to help drive innovation in medicine.

Tactics: In concert with other communications initiatives, actively reach out to health care professionals to see their input on relevant topics, and champion the role PAAB plays in supporting credible advertising.

Objective 3.2: PAAB is well-informed about industry and regulatory developments, and has the competencies needed to review emerging products

Although new drugs are not being developed at the pace they once were, pharmaceutical companies are moving into new areas of product development, including biologics and nutraceuticals.

To keep pace with industry, PAAB needs to proactively identify new product areas, and take measures to learn about them before companies begin seeking pre-clearance approval for their ads. By keeping staff competencies current, and being ready to review advertising for emerging products, PAAB can reinforce its value proposition to industry, healthcare providers, and regulators.

Not taking these steps creates a risk that companies will opt out of the PAAB process, or that regulatory or other bodies will seek to fill the gap.

Tactics: Develop and implement a strategy—including dedicated staff resources—to actively monitor and prepare for industry-related developments.

“To stay relevant, we have to give people what they need, in the form that they need it. Academic research

is moving faster than the regulatory system, and if we stand still, we risk becoming obsolete.” — PAAB Strategy Development Session, November 2016

Goal 4: Operational Excellence

PAAB is recognized as a model organization for independent review agencies operating in a regulatory environment

PAAB has established itself as a service-based organization that takes pride in meeting the highest standards of service delivery. PAAB's operations are supported by professional administrators who ensure that our technical, financial, and human resources systems meet our organization's needs. Maintaining this tradition of operational excellence will help PAAB reach its goals, now and into the future.

Objective 4.1: PAAB has modern tools to support excellence in service delivery

Industry depends on PAAB to review its submissions efficiently. PAAB reviewers take an average of seven business days to the first review and response of submissions, from a high of 20 days in 1996. They made these gains despite an increase in the number and the complexity of submissions they receive, and without compromising the integrity of the review process. In 1977, 25% of submissions were accepted in the first pass. In 2015, 23% were accepted in the first pass. The introduction of electronic filing in 2007 was a huge contributor to PAAB's efficiency. To keep this system working smoothly, we need to ensure that our IT systems are upgraded.

Tactics: Develop and implement an operational plan that includes targets for implementing the remaining recommendations of the governance review.

Objective 4.2: PAAB demonstrates continuous improvement in how it manages its business

In 2013, following the direction in the last strategic plan, PAAB undertook a governance review to assess its board structure and governance model and identify opportunities to improve. Some recommendations from the review have already been implemented, but some are still in progress, and some have not been tackled yet. However, some recommendations are intricately linked, which means that the benefits won't be realized until they are all complete. For PAAB to function at its best, we need to make deliberate and strategic decisions on which of the remaining recommendations we should implement.

Tactics: Develop and implement a plan and timeline for upgrading our IT infrastructure.

Conclusion

By definition, a strategic plan establishes goals that articulate what we want to achieve. PAAB's strategic goals guide how we will use our mission to help us achieve our vision. The objectives underneath these goals make them more tangible and quantifiable, and the tactics describe specific actions or activities that we will take to achieve them.

Developing the strategic plan is only the first step in the process of bringing those tactics to life in PAAB's day-to-day to work. To make real progress, we need to elaborate on these tactics in an operational plan that will identify the specific steps needed to successfully implement our tactics, along with timelines that will help keep us accountable. We also need to develop performance measures that will help us assess whether we are achieving the results we want.

All of these steps are part of a well-managed planning and reporting cycle that will allow PAAB to use this strategic plan the way that it's meant to be used—as a clear expression of who we are, where we're going, and how we plan to get there, together, to serve all of our stakeholders.