

The Pharmaceutical Advertising Advisory Board

REVIEW

Ray Chepesiuk, Commissioner



"It is the framework which changes with each new technology and not just the picture within the frame."

- Marshall McLuhan

We are all affected by technology. If you think back even five years, you will realize that we are doing things differently today in many areas. As pharmaceutical advertising and promotion changes, so do the regulatory agencies. I will discuss a few areas that affect the PAAB and you.

e-Files

The PAAB implemented an electronic document management system in January 2008. We hope you are aware of that because all submission files initiated after that date are required to be sent to the PAAB through our web portal. It involves a website (www.efiles.paab.ca) that is accessible to anyone who has access to the Internet. It was a year in the making and I commend the PAAB staff for getting through the adjustment. It was a major change in how we do our work and we appreciate the patience of our clients in making the transition to the new system. We also thank our supplier, Klick, for their development of the system.

We tried to develop an electronic system that replicated our manual system. Anyone who has lived through an electronic project that requires transition will know that it is almost impossible to do that completely. The user test phase was extended to correct a few major glitches that were obvious barriers to enhanced productivity, which was one of our goals of the project. The staff persevered through a busy last quarter of 2007, working in a parallel system and they maintained at 100% our promised delivery of first review of new submission files in 10 business days.

To use the system, clients have to register with the PAAB through Glenn Golaz at (905) 509-2275, extension 29. A client must have a registered user who maintains their own secure password to access their own account.

The PAAB staff has had five months to work with the system and are becoming more comfortable with it. We are entering a new phase of the project in which we will look at enhancements to improve ease of use and flexibility. Help us with your suggestions.





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Customer Experience Index

PAAB is a service organization. For the past number of years we have focused on delivering great customer service to the PAAB clients. That involves looking at what we do and how we deliver our service. We know we say "no" often and, of course, clients do not like "no" for an answer. PAAB staff members are selected for their skills and ability to do the work of the PAAB. They are trained to analyze advertising, make a yes/no decision, communicate that decision clearly in writing and then offer help to get to "yes," where applicable. Please be aware that our task is not to make you like the decision. Through better understanding of the regulations and the current marketplace, hopefully you will appreciate why PAAB makes the decisions it does.

As operations management guru Edwards Deeming said, "what gets measured, improves." Based on recommendations from expert human resource consultants who surveyed and analyzed PAAB operations, we have been making changes internally involving:

- adequate staff levels,
- how we train staff,
- how we communicate expectations to them and
- how staff is compensated for delivery of great service.

Externally, in the past two years we have reached out to our clients, asking them to help us improve our service delivery. We invited all clients to participate in an anonymous online survey in 2006. Our supplier, Pharmahorizons,

analyzed the results and identified five issues that came up most frequently. We addressed the five issues internally with PAAB staff and they have been working on improving PAAB delivery of customer service. To address those five topics with our clients, we had approximately 50 individuals from PAAB client companies participate in face-to-face discussions with the PAAB Commissioner and Chief Review Officer in four sessions in Toronto and Montreal in June 2007. We learned some specifics about the issues that were raised, realizing we could improve in some areas and also that some clients had misperceptions about the PAAB due to lack of knowledge. We received some suggestions to implement things that we have been doing for twenty years!

We are entering a new phase of responsiveness involving today's technology. Through the survey, focus groups and my own personal communications with clients, I have realized we have a great group of people working at the PAAB. We are always looking to improve and so we are developing a Customer Experience Index (CEI) with the help of Isaix Technologies. This involves you, our clients. Our system will randomly select completed review files each month and poll the clients who submitted them through a series of questions about their experience with the PAAB staff during the review process. They will be able to access a website to answer those questions. The client responders will be anonymous to the PAAB staff. We expect to hear good things and suggestions for the improvement of our customer service. So, if you get the email notice, please respond fully.

Web 3.0

I was just beginning to understand what Web 2.0 meant when I attended a great EPharma Summit conference in the US and heard about Web 3.0 and how it will affect healthcare and pharmaceutical marketing. In a nutshell, Web 3.0 is the marriage of social media networks (e.g., YouTube, Facebook, MySpace etc.) and permission-based databases of individuals interested in improving their healthcare. Web 3.0 is a brave new world with tremendous ramifications for helping to improve the delivery of healthcare. Presenters at the conference included high-ranking individuals from Microsoft, Google, Yahoo, SERMO and the



founders of AOL and Medscape®, not your usual list of healthcare providers. They want to change how healthcare information is provided to everyone. From my regulator vantage point, I was pleased to see that just about every speaker warned pharmaceutical companies to be aware of regulations that affected the marketing of pharmaceuticals because they applied to this new way of doing business. At a separate regulatory conference in the US, I learned that the American public trust level in pharmaceutical companies is at an all time low and the regulatory noose is tightening. The pharmaceutical industry is under siege by Congress, the Department of Justice, Health and Human Resources, Office of the Inspector Generals, State governments and attorneys general, the Securities Exchange Commission and the Federal Bureau of Investigation. Pardon me if I missed somebody.

Emphasis on off-label cases and involvement of medical academics is the subject of the next wave of prosecution activity. Consider yourself fortunate in Canada to worry about Health Canada, PAAB, Rx&D, Patented Medicine Prices Review Board and some provincial formularies. You may not know how good you have it here.





motivation matters



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