Help Us Help You

The Pharmaceutical Advertising Advisory Board

REVIEW

Ray Chepesiuk,
Commissioner

With the goal of fulfilling its mandate, PAAB serves a two-headed monster. One head is Health Canada which endorses the PAAB-directed self-regulation pre-clearance review program. The main issue for Health Canada is the quality of the reviews, with a strict adherence to federal law. The other head is the pharmaceutical industry and the PAAB clients. The main issue for the PAAB clients is the efficiency of the pre-clearance review, *i.e.,* "If we have to follow the process, make it fast."

I will devote this article to explain how PAAB tries to make it fast, discuss some of the limitations, and offer some tips on how you can help us to speed things up. At the time of writing this article, PAAB has had its fifth straight year of record review volume, although the final number was not in. We have added staff during these years to handle the workload and we have adjusted administrative procedures to help us help you. We strive to provide effective, efficient service.

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PAAB has many clients, consisting of around one hundred health-care product companies and over one hundred and twenty-five agencies. We review files as they are received. The Code of Advertising Acceptance cites a maximum 10 working days turnaround time for a first review. We have hit that target 93% of the time in 2005 and we are striving to do better in 2006.

We have created a submissions form to help standardize the review requests. We ask that you use the form every time you send a review request to PAAB. You can download a copy of the form from ***www.paab.ca.*** You can also find the PAAB fee schedule on our Web site.

We ask that you send us a complete submission to allow us to start and finish a review at one time. We will review what the advertising sponsor believes to be the final copy acceptable to the PAAB code. That is why the submissions form has a space for you to sign, confirming that the medical/regulatory department has approved this as the final copy. Some agencies have sent the "final" copy to PAAB and their sponsor at the same time. This leads to further revisions and increased administrative workload for the PAAB staff that should not be necessary. Consequently, we place those files in the queue by the date of the revision, *i.e.*, they have lost their place in the queue. This takes away the temptation for agencies to rush something to PAAB to "get a spot in the queue."

The PAAB staff can accommodate pre Notice of Compliance (NOC) launch meetings to help you determine what can be acceptable at PAAB. Sometimes we will say "no" if we are busy or if we believe that a meeting is not necessary. What we like to see and hear is a presentation outlining the current marketplace reality with data, a summary of the product monograph and pivotal clinical trials, and the marketing direction that will be used. The information is all confidential. This helps the reviewer to sift through all of the paper, once it arrives with the submission, and to know what is important.

Clients can request concept meetings during which we can discuss in confidence proposed creative for new advertising. We do charge a fee for these meetings. Of all the meetings we have, I think these are the most fun.

You can ask questions. Verbal answers are free of charge while written answers are done for a fee. If the question involves specific material, we will ask to see the material. This can help you prepare your material in a manner that is acceptable to the PAAB code and speed it through the review process. If you have administrative questions about the review process, please ask for one of the administrative staff rather than a reviewer.

When you send us new material to review, we ask that you quote previous PAAB file numbers that may contain the same claims and data presentations. Highlighting references and coding the copy deck to the reference material can help PAAB to get through a review more efficiently. When you make changes that we didn't ask for, please highlight them in the revised copy deck to bring it to the reviewers' attention. If there is recurrent copy that was the subject of a request for change, please make the changes to all of the affected copy parts.

As Commissioner of PAAB, I recognize that excellent customer service is a primary goal and I try to instill that in the PAAB staff. We cannot always say "approved" to copy that is presented the first time. We can however help change that "no" to a "yes." That is what the "advisory" in PAAB means. CPM