Common Sense for the Common Interest

The Pharmaceutical Advertising Advisory Board Review

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Common sense is not so common.
- Voltaire -

Sometimes, I believe Voltaire's comment to be true with respect to some pharmaceutical marketing practices. In this article, I would like to discuss a couple practices the PAAB advises against, yet are ongoing in Canadian pharmaceutical marketing. So far, only a few companies have engaged in these practices and we are trying to provide information that would discourage others from following.

"They who complain most are most to be complained of" (Matthew Henry)

The PAAB complaint resolution mechanism is designed to resolve complaints in a timely manner to keep the level playing field of the marketplace. It is labour-intensive and time-consuming for the individuals on all three sides, who are intimately involved in the letter-writing process.

Common sense about using this mechanism should prevail. A check of the PAAB complaint database reveals companies that complain the most are also on top of the list of companies who get complained about. The database shows some companies use the tactic of constant complaints versus their competitors. Unless those complaints are meaningful in their intent to stop bad promotional practices, why pursue them?

I have seen cases of companies making a complaint weeks after they get notified about a complaint made against them. Often, the complaint is focused on an activity that happened months ago. Why bother creating bad feelings by a retaliatory effort?

Many people have told me certain companies offer a "bounty" to their representatives to come up with material on which they can base a complaint against a competitor.

To substantiate a complaint, you must provide good evidence. Telling me representatives are handing things out at exhibit booths is not enough. Sometimes, we ask for an affidavit signed by a witness physician that an activity occurred. Remember, the PAAB can keep the name of the physician witness in confidence.

Seeding trials

This type of activity often involves entrepreneurial suppliers who sell their idea to unsuspecting or indifferent product managers. Complaints about these activities are appearing on the agenda at the Rx&D complaints committee meetings.

The PAAB reviewers have also identified some of these programs during review of material that advertises them to physicians. Pharma companies refer to them by different names, such as compliance programs, physician prescribing reviews, patient experience programs, naturalistic observational

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postmarketing studies, *etc*. Basically, they are similar in that there is some form of payment or incentive to physicians or patients for the creation of a new prescription for the sponsor's product, allowing product growth. Hence the name, "seeding" trial.

I believe, if you are engaging physicians to write prescriptions for patients and measuring the response, it is a clinical trial. Therefore, all of the medical and regulatory requirements of conducting clinical trials in Canada should be followed. Paying for prescriptions to be created has pitfalls.

It appears a pharma company is paying the physician for the "administrative" work involved in creating the patient record and, yet, the physician is probably billing the province for the same thing. Would you want your family doctor to be involved in this type of activity?

I recommend that pharma companies rethink practice of paying doctors to write prescriptions for their product in some form of disguise of clinical or market research. In the U.S., the Department of Justice has publicly stated they are looking for pharmaceutical fraud cases, including clinical research, market research, and off-label "educational" activities.

PAAB reviews common sense

A few common sense items have been identified by the PAAB reviewers and brought to my attention.

We thank companies for co-operating with making an appropriate type size for the fair balance safety and regulatory information that the PAAB Code requires in advertising. There have been some cases where companies decided to shrink the study parameter and disclaimer footnote information to an illegible size in compensation for the larger fair balance type size. Please don't do that! It will slow down the review process unnecessarily. Know the PAAB Code and plan your creation better to allow space for essential information.

Please abandon the thought of pre-notice of compliance (NOC) "marketing". That is illegal. There are some pre-NOC activities that involve *information* as opposed to *advertising* that you can do.

Seek advice. You can ask the PAAB for an opinion on your marketing ideas before you proceed. Use the newspaper analytical technique. Ask yourself, would I want to see what I did appearing in the front-page headline of a national newspaper?

Some common sense advice

I have often heard the statement, "no matter how much good it can do, the pharmaceutical industry will always find a way to shoot itself in the foot".

During my time at the PAAB several companies have provided evidence for that statement. Read the PAAB and Rx&D complaint reports to see what is happening in the marketplace from a regulatory point of view and adjust your marketing practices accordingly. CPM