PAAB Code Review

The Pharmaceutical Advertising Advisory Board

REVIEW

Ray Chepesiuk,
Commissioner

At the time of writing this article, we had just completed the survey of PAAB stakeholders regarding the proposed Code revisions. The findings mainly supported the proposal for the prescribing information format changes. There was a strong majority in favour of the proposal and a strong majority stated that the Code wording was clear and easy to follow. Of course there were suggestions for improvement and the Code committee will be looking at those and deciding on the merit of the suggestions. There were no big surprises in the input and, in general, the support was nearly as strong as the support shown in the 100-physician survey conducted by Ipsos Camelford Graham.

The next steps (probably to be completed by the time of this publication) include:

- review of the comments and suggestions by the Code committee,
- re-writing the draft to incorporate changes suggested by the Code committee,
- dissemination of the Code revisions to the PAAB members prior to November 24, 2006,
- voting on the proposed code revisions by the PAAB members on November 24 and, if yes,
- an implementation date and plan to be agreed on.

We intend to implement the Code revisions in a phased manner, with a deadline to make the changes. Also, we will be doing training sessions to discuss implementation of the Fair Balance Code changes. So, look for information from the PAAB in early December announcing the results of the board vote and our implementation plans.

There were no big surprises in the input and, in general, the support was nearly as strong as the support shown in the 100-physician survey conducted by Ipsos Camelford Graham

Electronic submissions

PAAB will be accepting electronic submissions in 2007. The PAAB Executive Committee agreed to a request for proposal process in October 2006 and the selection of the supplier in late October 2006. Budget approval at the November 24, 2006 general meeting is required. We are looking for a supplier to provide software and training to implement an online document management system.

The first phase would be to create a PAAB portal that could receive and review submissions entirely in an electronic format. The second phase would be to have the reviewers adopt a system that involves less paper than we utilize now during the review process. The third phase is in my head and not ready for prime time. I believe we can implement phase one

and phase two in 2007. The electronic platform can lead to review and administrative efficiencies and increased client satisfaction. When I have mentioned this to some company personnel, I was surprised how excited they were to hear our news. Stay tuned for more information.

Off-label

In September 2006, I had the pleasure and honour to present the Canadian advertising regulatory system at a conference in Philadelphia. The conference, titled the *5th Annual Off-Label Usage Conference,* was held at a wonderful venue, The Union League. Many of the speakers focused on the perils and pitfalls of breaking the rules in the US. Certainly, a different atmosphere prevails in marketing pharmaceuticals in the US today than five years to 10 years ago. I think the US companies impose pretty strict boundaries on what marketers can do these days. That is a result of the application of the False Claims Act and the Whistleblower Act in the US Personal culpability has come to the fore and people are not as ready to take one for the company if it means going to jail. There has been a big cleanup in the past few years at both the corporate and individual levels. I was fortunate to meet several Department of Justice employees who were directly involved in prosecuting large settlement cases. I also met lawyers who were prominent in handling *qui tam* (whistleblower) cases.

We do not have similar laws in Canada that the pharmaceutical industry has to worry about. However, I suggest that the Canadian industry keep following the advice set forth in the PAAB Code and the Rx&D Code and there will be no need to change the current laws. If society sees a need, the regulators will change the laws. Big Pharma appears to be an easy target these days.

CPM

Announcement

Robert Hamilton joins UCB Pharma Canada Inc.

Robert Hamilton, UCB Pharma Canada Inc.

Olav Hellebo, President, inflammatory operations, UCB, is pleased to announce the appointment of Robert Hamilton to the position of President and General Manager of UCB Pharma Canada Inc. In this newly-created position, Robert will be responsible for establishing, building out and leading the UCB affiliate in Canada.

Prior to joining UCB, Robert worked for over 20 years at three other large Canadian ethical biopharmaceutical companies in a number of senior sales, marketing and general management roles. A native of Kingston, Ontario, he holds a BSc (Honours) and MBA. degrees from Queen's University. He will be located in UCB Pharma Canada's offices in Burlington, Ontario.

Founded in 1928 and headquartered in Brussels, UCB is a leading global biopharma company dedicated to the research, development and commercialization of innovative pharmaceutical and biotechnology products in the fields of central nervous system disorders, allergy/respiratory diseases, immune and inflammatory disorders and oncology. UCB is driven by the passionate desire to help people living with severe diseases so that they can enjoy normal, everyday lives.

In 2005, UCB had revenues of over $3.3 billion, with 8,300 employees operating in 40 countries worldwide. Key commercially-available UCB products include the antihistamines Zyrtec® and Reactine® as well as the anti-epileptic agent Keppra®. Excellent phase III clinical trial results for CIMZIA™ in the treatment of Crohn's disease and promising developments in rheumatoid arthritis and psoriasis have encouraged a global expansion at UCB. UCB Pharma Canada has been incorporated to commercialize this novel biotherapeutic agent.