



The Pharmaceutical Advertising
Advisory Board

REVIEW

Ray Chepesiuk,
Commissioner

The Legal Looking Glass

“Law cannot stand aside from the social changes around it.”

— William J. Brennan

At the time of writing this message, Canada was headed into an election. And because of that, pending legislation is lost. One of the bills lost was Bill c-51, an effort to modernize Canada's health protection act and regulations. It would have replaced the current health protection laws. If the Progressive Conservatives return as the government, I would bet that the legislation will be resurrected, because after all, it had been ten years in the making. The last major change was over 55 years ago and society has changed tremendously during that time. Laws should reflect societal values.

In my talks to industry personnel, I have learned that there is not a high level of awareness of regulations and the real potential for change. I thought it would be a good idea to tell you a bit about it in a highlight presentation.

First of all, contrary to newspaper reports when the legislation was announced April 8, 2008, there is no apparent change to the direct-to-consumer advertising (DTCARx) regulations. Health Canada officials have confirmed that.

What critics of DTCARx got excited about was the fact that much of the legislation would be put into regulations rather than the Act itself. This would facilitate changing the law as necessary. Some misinterpreted the intent of this change in the DTCARx realm as being a loosening of the regulations. Not necessarily so. However, we do not know how Health Canada will use this feature to change regulations in the future.

Another major change would be the granting of provisions for enabling a progressive licensing approach to the regulation of health products. There could be differentiation between different types of categories of health products. There would be an onus on manufacturers to provide data to Health Canada throughout the product life cycle.

Schedule A (a list of diseases for which health claims to the general public cannot be made) is repealed. There is a new list of diseases and a lifting of the restriction on prevention claims that will allow non-prescription, natural health and some biological products to make claims to consumers.

Another big change would be to enable the list of prescription drugs to be amended through a ministerial order in council, which would

considerably shorten the regulatory process for switches.

The minister would be permitted to grant market authorization, when the benefits of a therapeutic product outweigh its risks and to authorize the use of risk management tools such as labelling and packaging requirements to mitigate safety considerations.

A significant change will be in the area of enforcement that will give the government a broader range and more severe penalties for violations of the law.

It will include tampering as a criminal offense with substantial penalties for tampering or hoaxes.

A significant change will be in the area of enforcement that will give the government a broader range and more severe penalties for violations of the law. The government will have authority to issue “ticketed” fines, mandate product recalls and assess fines to a maximum of \$5 million. The government will be able to mandate adverse event reporting from hospitals. During the preparatory phase leading to the legislation, we talked to Health Canada officials about alternative dispute resolution. I think the PAAB does that well.

Given the change in the political scene, we are not sure when this legislation will come into effect. However, I would bet that the next round of changes won’t take 55 years and I suggest that the pharma industry be prepared for change. **CPM**

Announcement

Christian Roy Appointed Vice-President, Marketing, Pfizer Canada



Christian Roy,
Vice-President,
Marketing,
Pfizer Canada

Christian Roy has been appointed Vice-President, Marketing and member of Pfizer Canada’s Leadership Team (PCLT). This appointment became effective September 8, 2008.

Christian has been with Pfizer Canada since May 1998. During this time, Christian has worked in numerous cross-functional leadership positions in Marketing, Market Access and most recently, as Director of Sales for Quebec and the Atlantic Provinces.

Christian is a strong commercial strategist with a consistent pattern of success. Most recently, Christian played a key role in the re-structuring of the Field Force and the evolution of new, non-traditional capabilities within the Sales Division. Another noteworthy achievement was Christian’s leadership of the Coxib team during very challenging times created by the Vioxx and Bextra withdrawals. Christian’s leadership resulted in minimizing the negative impact on our customers (physicians, pharmacists, wholesalers) and for members of the Field Force.

Christian’s appointment is a testament to his success and his leadership skills. The Marketing Division will benefit greatly from Christian’s well-rounded experience base, skill set, leadership ability as well as his integrated approaches to cross-functional solutions.