

August 12, 2009

Anne Sztuke-Fournier
Manager, Regulatory Advertising and Risk Communications Section
Health Canada, Marketed Health Products Directorate
Therapeutic Effectiveness and Policy Bureau
200 Tunney's Pasture Driveway, Tunney's Pasture
Ottawa, ON K1A 0K9

Re: Interim Guidance on Fair Balance in Direct-to-Consumer Advertising of Vaccines

Dear Ms. Sztuke-Fournier,

Members of the BIOTECanada Vaccine Industry Committee (VIC) read with interest the letter dated July 15, 2009 and the accompanying draft Interim Guidance entitled "Fair Balance in Direct-to-Consumer Advertising of Vaccines" which you kindly forwarded for industry review. The intent expressed by Health Canada in the "General Guiding Principles" of the draft Interim Guidance is fundamentally consistent with the VIC members' opinion on the subject of Direct-To-Consumer (DTC) advertising. Indeed, VIC agrees with Health Canada on the need for DTC advertising to clearly present useful information on both benefits and risks of specific vaccines in order to promote and facilitate sound health decisions about vaccination among the targeted audience. However, it is important to recognize that DTC advertising of vaccines may take place through a wide variety and scope of media and formats, with varying constraints and capabilities for conveying information.

Specifically, obvious differences exist between print material, internet-based promotion elements and broadcast advertising (radio and television). In terms of content capacity, print materials and some internet-based promotion elements allow a significantly larger volume of information to be conveyed than broadcast pieces and small internet elements such as "banner ads." Even among print materials, the variety of sizes and designs impacts the amount of useful information that can be reasonably and effectively included. Similarly, a clear distinction can be made between the same two types of promotional media in terms of the time of exposure to the information for the target audience. Understandably, the time of exposure directly impacts the amount of information that can be conveyed to and understood by the audience. For example, print media allow the reader to spend as much time as needed to carefully read a significant amount of information, whereas broadcast messages, by their passive and brief nature, provide room for more limited amounts of detail and require more concise information messages.

In Canada, vaccines can only be received, taken or administered upon consultation with a qualified healthcare professional. It is the opinion of the VIC that an advertisement cannot replace the thoroughness and patient-specificity of a discussion between a healthcare professional and potential recipient of a vaccine. For this reason, the information presented in a DTC advertisement should be primarily intended to making individuals aware of the availability of a vaccine and its intended use.

“Fair balance” in such a context should be suited to the chosen medium and to the ability of the targeted audience to take in and benefit from the information presented, as well as direct the targeted audience to the appropriate sources available for additional complete, objective and balanced information about the risks and benefits of the product.

Therefore, VIC members are of the opinion that in order to fully meet the intent of usefulness and objectivity of the information provided in DTC advertising, the requirements for “fair balance” content should allow flexibility and adapt the standards to the type of advertising medium and format. VIC members suggest that the Interim Guidance for DTC advertising be inspired from the regulations on labelling contents (*Food and Drugs Regulations, article C.01.004*), defining general requirements for “fair balance” for DTC advertising, but also providing minimum requirements for advertising media and formats with limited information capacity (at a minimum, television and radio advertising, and short internet-based advertising), with respect to which the general requirements for other advertising media and formats may not be reasonable or suitable. This proposal is consistent with agreements recently reached between some of the VIC member companies and Health Canada on satisfactory “fair balance” in television DTC advertising, and which the VIC members would like to propose as a basis for “fair balance” requirements on DTC advertising of limited information capacity as applicable:

- An explanation that everyone may not be fully protected by the vaccine (e.g. “as with all vaccines, 100% protection may not be guaranteed”)
- A warning that the vaccine may not be suitable for everyone (e.g. “there are certain individuals who should not receive the vaccine”)
- A warning of the possibility of adverse events (e.g. “some persons may experience side-effects”)
- A recommendation to consult with a physician to confirm the suitability of the vaccine (e.g. “talk to your doctor to see if VACCINE X is right for you or your child”)
- A reference to another source of additional, complete, objective and balanced information (e.g. “go to WEBSITE X for more information, including a copy of the Consumer Information Leaflet/Product Monograph”)

Again, BIOTECanada VIC members appreciate the opportunity to provide comments on the Interim Guidance and we look forward to further discussions with Health Canada on this issue.

Sincerely,



Marise Lemieux
Chair, BIOTECanada Vaccine Industry Committee