

Industry Alert on Advertising Standards Canada and Health Canada's use of Advertising Preclearance Agencies to Adjudicate Advertising Complaints

Prepared by Shawn Buckley, LL.B., president of the Natural Health Products Protection Association on February 29, 2012.

Key Points

- Health Canada has delegated the investigation and adjudication of advertising complaints to preclearance agencies like Advertising Standards Canada.
- If your advertising violates the Act or Regulations, providing preclearance agencies with information should be done with caution.
- If in doubt obtain legal advice before providing information that could support a conviction or which contains sensitive trade information which is not protected under the *Access to Information Act* when provided to non-governmental agencies like Advertising Standards Canada.

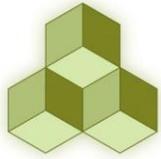
The Prohibition Against False Claims

Section 9 of the *Food and Drugs Act* makes it an offence to make false or misleading claims. It is a criminal offence to violate this section. Penalties can include incarceration. The section also deems a label to be false and misleading if it is not labeled in accordance with the regulations. The word "label" includes advertising that accompanies a product at the point of sale. It is not clear if this deeming provision would stand up in Court as it could lead to jail without the type of knowledge usually required for incarceration.

What is clear is that the section prohibits false and misleading claims. Caution should be exercised to ensure that all advertising is true. At the same time, section 9 does not limit persons to claims approved of by Health Canada in NHP licenses or temporarily with Exemption Numbers. If Health Canada was to prosecute under section 9, they would have to prove beyond a reasonable doubt that the advertising was false or misleading.

Health Canada's Use of Advertising Standards Canada

On September 30, 2010, Health Canada issued a policy titled "*Health Canada's Position Statement on the Preclearance and Complaint Adjudication of Exempted Natural Health Product Advertising Materials*" (the "Policy"). Under this policy Health Canada is in effect delegating to advertising preclearance agencies the task of vetting NHP claims and adjudicating complaints about NHP advertising for products with Exemption Numbers.



When Advertising Standards Canada ("ASC") accepts a complaint about advertising it sends an authoritative looking letter to the company advertising. According to the *ASC Clearance Services Drug Complaint Preclearance re Therapeutic Claims Policy*, ASC is to identify the advertisement that in their opinion does not comply with the law, and to request that the advertising immediately stop. In one letter we have seen the ASC:

- cites the Policy as their authority;

requests copies of the Product Licence Applications ("PLAs") as well as a signed letter from a senior regulatory official attesting that the PLAs provided to ASC are in fact the same PLAs for which Exemption Numbers were granted;
- imposes a deadline of 8 days to comply, and
- threatens to send the complaints to Health Canada if the deadline is not met.

It is likely that in many cases ASC will actually have received the complaint from Health Canada. In the case cited above ASC would not disclose the complaint(s) or the identity of the complainant(s) despite their written policy to disclose the complaint in their initial letter.

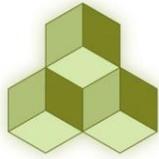
Legal Issues You Need to be Aware of Before Responding

According to Health Canada's Guidance Document *Health Canada and Advertising Preclearance Agencies' Roles Related to Health Product Advertising*, ASC is to refer back to Health Canada any complaints it investigates which in their judgment contravene the *Food and Drugs Act* or Regulations if they are unable to achieve compliance. This means that if you are the subject of a complaint and you disagree with ASC, the matter, **including your responses to ASC** will go to Health Canada. This undermines some key legal protections that you have when dealing with Health Canada that do not exist when dealing with ASC.

When Health Canada does not believe you have committed an offence, persons designated as Inspectors under the Act can in some circumstances demand information and documents and you have a legal obligation to comply (see s. 23 of the Act). However, once an Inspector believes that you have contravened the Act or Regulations, in most cases the investigation becomes criminal in nature and there is no obligation to provide information. Indeed, at that point the *Charter of Rights and Freedoms* (the "Charter") applies, including the right to silence and the right to be free from unreasonable search or seizure.

So if Health Canada believed you were advertising in contravention of the Act or Regulations, they would not have the right to demand information, and the protections of the Charter would apply.

The ASC is not government and so the Charter does not apply. If you comply with their demands, such as having a senior person sign a verification of submitted PLAs, that information could then be sent to Health Canada and likely could be used in a prosecution.



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By way of analogy, if the police delegated their impaired driving investigations to a non-government body such as Mothers Against Drunk Driving, all of the Charter protections that apply when persons deal with the police would not apply. Similarly, by delegating investigation of advertising complaints to ASC, Health Canada has placed you in a position where you may be asked to provide information which could later be used in a prosecution, without any of the safeguards that would apply if you were dealing directly with Health Canada.

The information you provide to Health Canada is also protected under the *Access to Information Act*. In the case cited above, the ASC demanded complete copies of a number of PLAs. The protection of trade secrets under the *Access to Information Act* that apply to Health Canada do not apply to the ASC.

There is a very real possibility that Health Canada's delegation through policy, as it is currently set up, is not legal. We have not, however, done a legal analysis on this point.

In some cases it may be preferable for you to try to adjudicate a complaint through the ASC rather than deal with Health Canada's Inspectorate. However, we strongly recommend that you obtain legal advice and be careful not to provide information that could then be used in a prosecution or which is sensitive trade information.