The Use of Social Media by the Drug Industry in Canada, and Comparison with U.S. Laws

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The Internet in general, and social media in particular, is changing advertising. Drug advertising is no exception. Consumers are increasingly turning to the Internet for health-related information. In 2009, 70% of Canadians turned to the Internet for health-related information, and 92% of those used the search engine Google, rather than a health portal to gather this information.[1] Furthermore, social media has permanently changed the way we consume and share information. Platforms such as Facebook and Twitter have hundreds of millions of users. However, the drug industry has been proceeding cautiously in taking advantage of social media advertising, while waiting for regulators publish clear policies. Nonetheless, the industry has begun carefully advertising using the new media. For example, race car driver Charlie Kimball (who is a diabetic) partnered with Novo Nordisk to prove that he can pursue his high-performance career using insulin. As part of the ad campaign, Kimball tweeted the drug's generic name and a link to information about the drug's risks and benefits.

This article gives a broad overview of the Canadian regulatory framework and guidelines that affect the advertising of pharmaceuticals in social media; it also provides some enforcement examples and discusses general compliance issues, including spillover advertising. The article then concludes with a brief comparison between U.S. and Canadian laws.

Regulatory Overview

Social media is more complex and harder to regulate than traditional media. Traditional media is built on a "one-to-many" (e.g., newspaper to subscribers) model, whereas social media operates on a "many-to-many" basis. Today, users do not simply consume media – they also generate media content through, for example, Twitter, article comments and blogs. Social media also delivers information fast and personally to consumers. Despite this complexity, the laws that govern drug advertising in social media are the same laws that govern advertising in traditional media.

In Canada, the relevant laws are the *Food and Drugs Act* and its regulations (*Food and Drug Regulations* and *Natural Health Products Regulations*), the *Competition Act* (which prohibits deceptive representations to promote a product or business interest through misleading advertising and labeling provisions), the *Trade-marks Act*, the *Copyright Act* and common law.

Guidelines and Codes

Canada has two sources of drug advertising guidelines. The first is Health Canada, which has stated that it is not planning a special guidance document for social media advertising.[2] Instead, Health Canada's general advertising policies are intended to apply to social media.

The second source of guidance is preclearance agencies. These agencies are putting more effort into updating their advertising standards to cover social media.

The Pharmaceutical Advertising Advisory Board (PAAB) preclears advertising directed to healthcare professionals. Earlier this year, PAAB released a draft amendment of the PAAB Code.[3] The proposal is expansive and covers blogs, Twitter, chat rooms, YouTube, Flickr, Facebook, podcasts, smartphone apps, brand and corporate websites, RSS feeds, user-generated content (e.g., a "like" rating on an article), etc. Several of the proposed changes are worth highlighting.

Draft section 6.5 would require a preclearance review by PAAB if the media form, or part of it, is under the direct control of a manufacturer. The draft proposal also requires that industry-sponsored websites, platforms or networks introduce access controls. The proposal would require the sponsor to determine whether the user requesting the online information is a physician, patient or consumer. The information accessible through the site would depend on the type of user. For example, sites directed at patients would be password-protected, and the sponsor would control the password distribution.

The draft proposal requires that the sponsor of a pharmaceutical company disclose its name on every website and on every

sponsored webpage of a website that has no access control. The new provision would also require banners and pop-up ads with direct or implied product claims to include both a risk/benefit fair balance statement and a link to the complete product monograph.

Advertising Standards Canada (ASC) preclears consumer advertising of prescription drugs, which is restricted to name, price and quantity. ASC has released a checklist for complying with the *Food and Drugs Act* in direct-to-consumer advertising, which includes social media.[4] The organization also released a guide that explains Health Canada's policies regarding the distinction between advertising and other activities.[5]

Enforcement and Complaints

Health Canada has neither published complaints nor publicly described its enforcement actions against drug companies advertising in social media. However the U.S. Food and Drug Administration (FDA) has issued warning letters to manufacturers sponsoring search engine ads for prescription drugs that did not include a statement of risks. FDA warned that access-to-risk information does not necessarily translate into a warning of risks. FDA also issued a warning letter to a manufacturer for making misrepresentations on a "Facebook share" widget by failing to disclose risks along with representations of the drug's efficacy.[6]

Compliance Issues

The use of social media by the drug industry raises several compliance issues. One potential issue is off-label advertising, whereby a drug is promoted for an unapproved use. For example, is a drug company liable if a user makes an off-label claim on the company's Facebook page or in a company forum? Another compliance issue is fair balance – that is, not overstating the benefits or understating the risks of a drug. However, it is difficult for a company to know how to comply with this requirement. Is it possible to provide "fair balance" in a 140-character Twitter post? Another potential issue is whether risk information is adequately disclosed by a one-click link? Or must all the risks be included in the same post promoting the product? Regulators are also concerned with transparency in social media advertising because it is difficult to ascertain who is sponsoring a particular ad in that context.

A prudent pharmaceutical company wishing to benefit from the advertising opportunities afforded by social media may wish to comply with the following checklist:

- Limit who can access the corporate Facebook account and restrict editing and access rights to those who speak for the company;
- Prohibit "stealth" marketing (e.g., praising the company's products and downplaying risks; disparaging competitors' products; commenting under unidentifiable names);
- Create a social media policy within the company (stealth marketing, confidentiality, etc.);
- Get comfortable relinquishing (some) control over the message;
- To compensate for the lack of control, develop a company policy to review social media for accuracy of information (e.g., correcting inaccurate user comments and posts);
- Get ahead of the regulatory curve – proactively monitor positions of regulators;
- Be prepared to make some mistakes and have a protocol ready for damage control;
- Be aware of intellectual property issues (videos, music, photos posted in social media); and
- Remember, general advertising laws that apply to traditional media apply to social media.

Spillover of U.S. Social Media Advertising to Canada

Canadians are constantly exposed to American television and radio advertisements. Spillover of U.S. advertising has always been an issue in Canada, but the new media has compounded this spillover. Health Canada's position is that it does not have jurisdiction over advertising originating outside Canada and spilling over into Canada.

U.S. and Canadian Regulators

FDA and Health Canada are largely silent on how the drug industry can use new media to advertise. However, in December 2011, FDA released a draft guidance resulting from a public consultation process held in 2009, but the draft has a narrow focus.[7] Since FDA has moved on this issue, Health Canada will likely follow suit. Once the rules become clear, we expect an explosion of drug marketing in social media.

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1. See Michael Law, "Online Drug Information in Canada," March 2012, online: www.paab.ca/local/files/MichaelLPAAB%20Report%20Final.pdf.
2. See Health Canada, "Record of Discussions - Canadian Advertising

Preclearance Agencies and Health Canada," April 19, 2011, online: www.hc-sc.gc.ca/dhp-mps/advert-publicit/meet-reunion/rod-rdd_2011_04_19-eng.php#a12.

3. See PAAB Code Review 2012, "Section 6.5: Online Activities," online: www.paab.ca/en/paab_code/paab_code_review/.
4. See ASC Clearance Services, "DTCA RX Checklist," online: www.adstandards.com/en/clearance/ConsumerDrugs/DTCA-ChecklistEN.pdf.
5. See ASC Clearance Services, "DTCI Guide – Brochures and Website," online: www.adstandards.com/en/clearance/ConsumerDrugs/DTCIGuideEN.pdf.
6. See FDA, "Inspections, Compliance, Enforcement, and Criminal Investigations," online: www.fda.gov/ICECI/EnforcementActions/WarningLetters/default.htm.
7. See Food and Drug Administration, "Guidance for Industry: Responding to Unsolicited Requests for Off-Label Information About Prescription Drugs and Medical Device - Draft Guidance," December 2011, online: www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm285145.pdf. It addresses only social media discussion of off-label medication use. The FDA proposes that a company should respond to unsolicited requests for off-label information only if it relates to its own product. The response should not include off-label information and should be limited to providing the company's contact information. A representative who writes a public response to an unsolicited request should disclose his or her involvement with company. All responses should be non-promotional in nature and tone.