Guidance document for Online Activities

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INTRODUCTION

The growing popularity of online forums to share information and connect with a virtual community poses unique challenges in the highly regulated pharmaceutical industry. The increasingly popular adoption of social networking sites is attracting drug manufacturers in greater numbers with a promise of increasing customer engagement.

Engaging in online forums is not without its risks particularly in the area of drug advertising, adverse event reporting and other challenges. This supplementary guidance document was prepared to assist drug manufacturers navigate the compliance issues inherent with this medium. The following proposals represent best practices suggested by PAAB to maximize the success of online initiatives. It is important to note that deviations from the recommendations included herein may be acceptable depending on the context and particular situation.

1 Overview of the Regulatory Requirements for Drug Advertising

The requirements for drug advertising apply to all activities that are considered promotional in nature regardless of whether these activities are online or use traditional media. To assist the sponsor in determining the regulatory requirements for online activities, this section provides an overview of the general requirements for drug advertising.

The material in this section is organized around four themes. Understanding how these themes work together will enable sponsors to make the appropriate choices and ensure compliance to the regulatory requirements for drug advertising.

The four themes include

- *The intent of the message:*
  Is the intent of the message to promote a drug, disease awareness or a company?

- *The target audience solicited:*
  Is the information targeted towards healthcare professionals, patients or the consumer?

- *The type of drug product:*
  Does the information pertain to a prescription, non-prescription, vaccine or natural health product?

- *The nature of the online content:*
  Does the site allow for dynamic content or is it static (i.e. entirely controlled by the sponsor)?

1.1 The Intent of the Message

There are 4 types of messages that can be disseminated. These include the following:

a. Drug Advertising
b. Medical and disease information
c. Corporate information and promotion
d. Education and learning programs

a. Drug Advertising:

Online sites that promote a drug product must adhere to the same requirements as traditional drug advertisements. The content will be dependent on the target audience (consumers, patients or healthcare professionals) and the type of drug product (e.g. Federal drug schedule).

Online information can be categorized as static or dynamic content. Static content is the information wholly controlled by the sponsor (such as wall posts or websites). Dynamic content includes the information provided by users in the form of posts and other online dialogue activity.

Whenever either content contains a reference to a drug product (regardless of type of drug) an evaluation as to whether the information triggers the drug advertising requirements must be conducted by the sponsor. For static content this is relatively straightforward but dynamic content requires that certain measures be adopted to avoid running afoul of the drug advertising rules. Section 2 of this guidance provides recommendations for sponsor oversight of the interactive content of websites.

b. Medical and disease information:

Many existing online sites promote disease awareness (e.g. diabetes) or therapeutic area (e.g. cancer) and are analogous to consumer brochures. Consumer brochures include disease information and the various treatments options (drug and non-drug) and are made available to consumers either directly via the sponsor or indirectly. These sites are not branded to any particular drug either by name (including synonyms) or visuals (such as fonts, colours, graphics, images etc.).

This type of information is not, in and of itself, considered advertising insofar as the requirements for consumer brochures are preserved (for a complete list, please see the Health Canada document "*The Distinction Between Advertising and Other Activities*"). However, if the dynamic content includes the emphasis on a particular drug, these statements may become attributable to the sponsor and jeopardize the non-promotional nature of the site. Consequently, sponsors must monitor the interactive content on their sites to ensure alignment to the regulatory requirements of drug advertising (see Sections 2 and 3 for recommendations of sponsor oversight).

c. Corporate information and promotion:

General corporate promotion includes institutional messages that are designed to highlight the activities of a firm and to provide information such as the product portfolio, financial information and areas of future development. Examples include press releases, price lists and development pipeline information. Although this type of information may contain the names of drugs it is not considered promotional as long as sponsors align their discussions to the limits of drug advertising as outlined in the Health Canada document "*The Distinction Between Advertising and Other Activities*".

d. *Education and learning programs:*

Events and/or material whose primary purpose is to enhance knowledge and understanding of advances in health research, health sciences, clinical practice and professional development so that healthcare professionals can, in turn, provide superior health care to Canadian patients. Refer to the Health Canada document "The Distinction Between Advertising and Other Activities" to determine whether the program falls within the advertising realm. Advertising directed to healthcare professionals requires PAAB review unless it meets the exemptions outlined in sections 1.5 Materials not Subject to Preclearance of the PAAB code.

1.2 The Target Audience

The appropriate classification of the target audience will greatly enhance a sponsor's ability to maintain compliance to the regulatory requirements for drug advertising. The nature and content of online activities depends on the audience that is being solicited. The three audiences include:

a. *Healthcare Professionals:* Licensed members of health related disciplines and institutions. For example, Licensed members of the professions of medicine, dentistry, naturopathy, homeopathy, nursing, pharmacy and other related disciplines

b. *Patients:* A person who has been prescribed drug therapy by a health care professional

c. *Consumers:* Members of the general public

When targeting messages to healthcare professionals and patients, appropriate measures should be taken to ensure that the content is not accessible by others. This is often referred to as "gating" a site. A gate requires user authentication.

For healthcare professionals this can be accomplished by using their provincial license number or a password distributed in a controlled manner by the manufacturer. For patients accessing a drug site, this can be accomplished by using the DIN or a password provided by the manufacturer through the healthcare professional. Note that answers to questions (e.g. "what is the maximum dose of drug X" or "what is the colour of your drug X tablet") are not acceptable gating mechanisms as the answer can be easily found by consumers. See other examples of inappropriate gating mechanisms below.

> ***Example #1 of insufficient gating barrier:***
> *A manufacturer or publisher wishes to promote immediate access to an HCP targeted medical website containing advertising exceeding the restrictions set out in Section C.01.044 of the Food and Drug Regulations. Therefore, a registration system is used as the "gate". The registration requires the user to provide information (an email address, profession, area of specialty, office contact info); there is no validation mechanism on the front-end. All registrants are granted immediate access to the site after they affirm themselves to be HCPs and back-end validation will occur within a week. If the registration information is later found to be inaccurate (i.e. user was not an HCP), the user will be prevented from re-entry.*
> *This mechanism would not provide a sufficient barrier as temporary Web site access would be granted to anyone self-affirming that he/she is a healthcare professional. Such*

a temporary access could be provided to the general public and would thus likely be considered a contravention of Section C.01.044 of the Food and Drug Regulations. Although we understand that critical information should be accessed by HCPs, there should be a mechanism in place ensuring that only genuine HCPs are granted access to the site right upon request. This could be done by implementing a system where HCPs enter their names and medical professional license number. If HCPs require immediate access to accurate medical information from the sponsor, they should be able to contact the Medical Information Department of the sponsor. Subsequently, any print or Web material relevant to the request could be sent directly to the requesting HCP.

Example #2 of insufficient gating barrier:
A medical journal website has gating based on an IP-address filter that identifies institutional subscribers (such as entire universities). While this will not allow access to the general public, it will allow access for all individuals associated with the institution, many of whom are not healthcare professionals or in related job functions. As such, an advertisement exceeding the restrictions set out in Section C.01.044 of the Food and Drug Regulations must not be placed on this medical journal website. This type of barrier does not sufficiently restrict access to non-HCPs.

1.3 The Type of Drug Product

The acceptable content of advertising messages to different audiences is based upon the type of drug product. There are some key regulatory restrictions that a sponsor needs to be familiar with and include the following:

Table 1
Major Regulatory Restrictions on Drug Advertising

Federal Schedule	Common Reference	Restrictions	Reference
Schedule Prescription	Prescription drugs	DTC advertising limited to name, price and quantity	F&DR C.01.044
		Cannot advertise a drug to the general public as a treatment or cure of a Schedule A disease	F&DA Section 3(1)
Controlled drugs & substances	Narcotics	DTC advertising is prohibited	F&DR G.01.007
Schedule D & Ethical	Biologics (including insulin) and ethical products	Cannot advertise a drug to the general public as a treatment or cure of a Schedule A disease	F&DA Section 3(1)
Schedule D	Vaccines	Cannot advertise a drug to the general public as a treatment or cure of a Schedule A disease but preventative claims are allowed	F&DA Section 3(1) F&DR A.01.067 Interim Guidance – Fair Balance in DTC Advertising of Vaccines
Unscheduled	OTC and NHP	Cannot advertise a drug to the general public for a treatment or cure of a Schedule A disease	F&DA Section 3(1)

- DTC: Direct-to-consumer advertising (e.g. television drug advertising campaigns)
- Schedule A: List of diseases and abnormal states that require the intervention of a healthcare professional for diagnosis and treatment (see complete list: at http://laws-lois.justice.gc.ca/eng/acts/F-27/page-13.html#h-18)
- F&DR: Food and Drug Regulations (http://laws-lois.justice.gc.ca/eng/regulations/C.R.C.,_c._870/index.html)
- F&DA: Food and Drugs Act (http://laws-lois.justice.gc.ca/eng/acts/F-27/)
- Interim Guidance – Fair Balance in Direct-to-Consumer Advertising of Vaccines: http://www.hc-sc.gc.ca/ahc-asc/branch-dirgen/hpfb-dgpsa/mhpd-dpsc/guidance-directrice_dtca-pdac_vaccines-vaccins-eng.php

1.4 The nature of the online content

In the online world, there are 2 types of content that can exist:

a. Static on-line content
b. Dynamic on-line content

a. Static on-line content:

Static online content includes information that is made available online, but does not allow for a user to modify or comment on the content. This includes web pages that deliver information that is completely controlled by the sponsor. Examples include:

i) The investor information section of a corporate web-site. These should be clearly identified as information intended for investors
ii) Press releases that are presented as “news” for a period longer than is practiced by valid online news providers e.g. Sympatico, Yahoo or online newspapers

The examples above should be non-promotional in nature and be consistent with Health Canada guidelines on advertising. Any drug promotion content would require PAAB preclearance review.

b. Dynamic on-line content

There are two types of dynamic online content:

i) *Site-generated content (SGC).* This type of content is initiated by the sponsor but may be presented to the audience by third-parties. Examples include, but are not limited to, blogs, webisodes, videos and articles

ii) *User-generated content (UGC)*. This includes the content/dialogue created by users in response to site-generated content. UGC can be found on the sponsor's site or other social media platforms such as Facebook, Twitter and YouTube

The presence of UGC on a sponsored property can render a compliant page non-compliant by the comments that have been made. If users begin an online conversation in regards to a drug product, those dialogue threads can be attributed to the sponsor and could be subject to the regulatory requirements of drug advertising. Section 2 of this guidance provides recommendation for sponsor oversight of the interactive content of websites.

Regardless of whether the site includes static and/or dynamic content, for promotional content, all the current rules, regulations, policies and guidance that exist for drug advertising and other activities apply equally to online dynamic content and content delivered via traditional media (e.g. journal ads). This includes but is not limited to, the fair balance requirements outlined in the PAAB code and guidelines.

1.5 Other Considerations

1.5.1 Search Engine Optimization and Marketing

Search Engine Optimization (SEO):
Sponsors should not provide the text of a meta data descriptor that contains direct or implied product claims to a search engine that would contravene any federal regulatory requirements for drug advertising. Any descriptor under the control of the sponsor, for patient and/or healthcare professional sites must be submitted for preclearance review. Keywords and other meta data tags that refer to competitor products are prohibited because it is deemed unethical. Metadescriptors in organic search results for schedule D products may contain claims; they do not require Fair Balance.

A “No Index” command must be used for every page behind a HCP or patient gating mechanism.

The requirements involve the relationship between the metadescriptor, the keyword, and the site/page. The PAAB does not concern itself with the ultimate ranking of organic search results.

Search Engine Marketing (SEM):
The meta data requirements are the same as Search Engine Optimization with the additional requirement that purchased keywords taken in context with the other material, not exceed the regulations.

1.5.2 Uniform Resource Locator (URL) considerations

The sponsor should not take steps to cause the composite of the user generated keyword, the metadescriptor, the landing page, and the URL to exceed that which is permissible (e.g. meta tags).

1.5.3 Banner ads, pop-ups ads and microblogging

Banner or pop-up ads that contain either direct or implied product claims must include risk/benefit fair balance and be page-linked to the product monograph.

2 Sponsor Oversight of Online Activities

2.1 General Considerations

In the social media world, issues can escalate rapidly into a crisis for the company. When online information is coupled with a user's ability to provide interactive content, the sponsor should exercise care in responding to individual users. Ensuring the proper oversight over these sites will greatly enhance a company's ability to respond quickly to any issue and to ensure compliance to the drug advertising rules.

For the purposes of this guidance document, the recommendations contained in this section will focus on those websites that include dynamic content.

2.2 Corporate Policies

The following elements will greatly assist in maintaining compliance to all applicable rules and sponsors are encouraged to develop corporate policies that address these elements.

Terms and Conditions: The sponsor should provide in a clear and accessible manner the terms and conditions for users to engage in UGC on a sponsored site with clear statements about what types of comments will be removed or modified. For example, a site may forbid any discussion of drug therapy and will remove any posts that include them.

Monitoring the Conversations: Sponsors must monitor the UGC to ensure that compliance is maintained. An effective monitoring strategy can also assist in managing the risk to the sponsor that is inherent when the content is opened to users. To improve the effectiveness of the monitoring it is recommended that sponsors use a semantic, automatic filtering mechanism (e.g. brand key words, side effects) if the social technology supports it. Specifically, monitoring, and correction on the same site, is recommended for the following:

a. *Correcting misinformation:* Users can post information that may be incorrect as to a disease state or its treatment. The sponsor should monitor the UGC to correct any misinformation. Given the need for such corrections to occur in a timely manner, they may be made without PAAB pre-clearance provided content is limited to that which is required to address the misinformation. Caution should be exercised when correcting such misinformation as to ensure compliance with the regulations.

b. *Adverse event monitoring:* As a complement to providing a statement referring reporters to the pharmacovigilance / medical department of the sponsor, it is recommended to include a reference for the reporting of adverse events directly to Health Canada and provide the relevant Health Canada web-site address and toll-free number.

c. *Off-label discussions:* Discussions of a treatment that fall outside of the TMA can occur in UGC. As the sponsor is fully responsible for the content of the site (including the content created by the community) failure to address off-label discussions will render the site non-compliant. Off-label discussions must be removed outright.

2.3 Ongoing Management of Interactive Content

a. *Ongoing monitoring of users' conversations*
   All postings by users must be monitored as per the directives set out in corporate policies to that effect. Postings on company sites should be promptly triaged in

accordance with the applicable corporate policy for determination of an appropriate response. Additionally, it is recommended that those individuals responding on behalf of the company receive specific training in the areas of adverse event monitoring and drug advertising.

As part of monitoring, online discussions postings that contain potential adverse event reports will need to be addressed according to established corporate policies and procedures for handling and reporting spontaneous adverse event reports. The Health Canada requirements, including follow-up to obtain the necessary elements needed to report an adverse event, will need to be addressed when appropriate.

b. *Removal and Correction of Misinformation (including off-label discussions)*
When visitors post comments that are in direct violation with the site's Terms of Use (such as posts mentioning specific products) it is recommended that the sponsor develop a process for removing these posts should these contravene the rules for drug advertising. It is recommended that sponsors develop standard responses for when a post needs to be removed.

c. *Responding to Requests from Individual Users*
Any product-related question from a user on a site not intended for product discussion must be responded to in a manner that is visible to the requestor only. In other words, the reply should not be made public. One-on-one correspondence is exempt from the rules of advertising. If a sponsor elects to respond to an individual user in a public forum such that all users can view the response, the drug advertising rules may be triggered.

Moreover, any request for information from a user for an unapproved product or for a use of a marketed product that is inconsistent with the TMA should be handled by the sponsor's medical information department.

3 Listening Related Activities

3.1. General Considerations

All companies find benefit in listening to their customers, and Pharmaceutical companies are no different. These guidelines discuss what is permitted when screening large amounts of information found on the Internet, called “listening” for the purposes of this document. This information can come from many sources such as:

- Social networks such as Facebook and Google+
- Forum topics and replies
- Microblogs such as Twitter
- Blogs and comments
- Mainstream news and comments
- Comments on media such as video, images, and slide decks

Pharmaceutical companies operate under Health Canada regulations and they must adhere to special restrictions and responsibilities when engaging in online listening. These guidelines are independent of where the information comes from or what tools may be used to acquire it.

Note: These guidelines do not cover best practice for social listening in general; they cover only the considerations for pharmaceutical companies.

3.2. Responsibilities

3.2.1 Product Safety

Listening activities in social media are treated the same as the proverbial “cocktail party”. If an agent of the pharmaceutical company discovers a product safety issue (product complaint or adverse event) then that issue must be reported per the company’s pharmacovigilance guidelines.

3.2.2 Competitive Information

When reviewing information about its brand, a company will often also review information about its competitors. Companies **are not** required to report product safety issues on other company’s products.

3.2.3 Listening Requirement

No pharmaceutical company is required to perform screening, monitoring, or social listening activities. It is recognized that monitoring the entire internet for information is impossible.

3.2.4 Listening

Pharmaceutical companies may choose to engage in research and “listening”. There are a large number of tools that can be used for this purpose from advanced aggregation

services such as Sysomos and Radian6 to lower end tools such as Google Alerts and simple Google searches. Use of these tools do not remove the burden of regulatory responsibility from the company. Any reportable product safety issues found through these tools must be reported through standard channels.

3.2.5 Responsibilities

A pharmaceutical company **is not** responsible for product safety issues that are held in a tool if they are “dormant” (i.e. not exposed) during research.
A pharmaceutical company **is** responsible for any product safety issues that are exposed during research.

Example one: a researcher sees a chart of mentions that shows a spike of interest on a certain date. The chart itself contains only volumes of brand mentions, so it does not need to be reported. The researcher reviews a sample of the mentions that make up the spike and finds that the conversation revolves around a press release about a new side effect for a drug. The mentions reviewed are exclusively news related; they do not contain personal experiences. The researcher does not have to report these mentions as safety reports.

Example two: a researcher sees a “word cloud” of terms connected to a pharmaceutical branded (or unbranded) name. This “word cloud” contains some prominent terms that could indicate product safety issues. At this point the researcher may be required to file a report based on the individual company’s pharmacovigilance guidelines if the brand and a particular safety issue are prominent, but is not required to report based on Health Canada’s regulations. The pharmacovigilance group will have guidelines about the requirement to investigate. Once the researcher looks at the conversations that make up the word cloud then any mentions that contain product safety issues must be reported as per the company’s pharmacovigilance guidelines.

3.2.6 Restrictions

The restrictions on listening are based more on the terms and conditions of usage of individual websites than Canadian health regulations. From a regulatory standpoint there are no restrictions regarding online monitoring.

3.2.7 Terms and Conditions

Websites may vary in their terms and conditions of usage and need to be respected by both the listening company and any tools they use.

4 CORRECTING AND/OR REMOVING MISINFORMATION ONLINE

4.1 General Considerations

a. As per the PAAB code 1.4.K, online activities must undergo PAAB preclearance review.

b. However, it is the responsibility of the pharmaceutical company that has produced the online APS to ensure the information presented is accurate as per the PAAB code 1.4.K – F) Privacy.

c. Any misinformation about a healthcare product found on a website produced and/or sponsored by a pharmaceutical company, must be corrected and/or removed by said pharmaceutical company.

d. This includes misinformation found on corporate websites, product-specific websites and sponsored websites.

e. Misinformation found on a site that has undergone PAAB preclearance review could result in the withdrawal of said clearance. For more information see the PAAB code 1.6.G) “Conditions for withdrawal of clearance.”

f. Misinformation must be removed or corrected at the earliest feasible date – taking into consideration what is reasonable with respect to operational concerns, or within the schedule set forth by the Commissioner, in the case of a PAAB ruling.

g. Pharmaceutical companies can also help to ensure the accuracy of information presented about their healthcare products found on third-party, independent websites.

h. When misinformation for a healthcare product is found on a third-party, independent website, the pharmaceutical company of said product may notify the third-party site of this error, in writing.

i. This notification must include specific details about what misinformation has been presented and the action required to rectify the situation, which can include either of the following:

   i. A request to remove the misinformation being presented.

   ii. Guidance on the appropriate wording to use to correct the misinformation being presented.

   iii. The manufacturer may also correct this information themselves as long as the communication is factual and follows the PAAB rules for communication to audiences (consumer vs. patient vs. HCP communication) as well as rules around adverting.

   iv. The correction should be made by the third-party site by the earliest feasible date.

5 Abbreviations & Definitions

Abbreviation	Description	Definition
APP	Applications	Programs that typically run on smartphones/tablets and are accessed either through download or through the App Store for the user's platform. When the APP store includes reviews of the app products, pharma should ensure that wording of reviews fall within the restrictions of Canadian regulations.
	Badge	A label that is attached to all interactions by a user to show something about them. This helps other users interpret their information more easily. This can be a flag showing that a user is employed by a pharma company on an HCP site or a flag indicating who is a moderator of a forum. Badges can be text or graphics Also, a reward for accomplishing a task which is then typically shared with friends. For example, a badge might be given for achieving a milestone such as 25% of the way to a health goal
	Bit.ly	One of a number of URL-shortening services that translate long URLs into short, obfuscated, ones for use on micro-blogging services. For example, http://bit.ly/ArkJKW forwards to www.paab.ca
	Brand Website	Also known as an APS Website. A website devoted to promoting a branded drug to one or more audiences.
	Consumer	A member of the general public who is neither a patient nor a healthcare professional.
	Corporate Website	A website devoted to discussing the corporation rather than any of its branded pharmaceuticals.
DIN	Drug Identification Number	The DIN is the 8 digit number located on the label of prescription and over-the-counter drug products that have been evaluated by the Therapeutic

Abbreviation	Description	Definition
		Products Directorate (TPD) and approved for sale in Canada.
HCP	Healthcare Professional	Any of a number of healthcare workers involved in delivering care to patients. Physicians are the most commonly-referenced HCP but Nurses, Pharmacists, and others are also included.
	Help-Seeking Ad	Help-seeking ads describe a disease or condition but do not recommend or suggest specific drugs. People with these symptoms are encouraged to talk to their doctor or contact an information source.
	Micro-blogging	The issuance of short, sub-140 character, messages instead of longer blog posts. Twitter is the most famous micro-blogging service.
	Patient	A person who has been prescribed or recommended a drug product and/or is being counseled on drug therapy by a health care professional.
	Retweet	The forwarding of another user's Tweet to all of the user's followers on Twitter.
RSS	Really Simple Syndication	A simple XML schema that allows readers to pull data and display it any way they choose. Used for blogs and press releases to expand the ways people can access the information.
SEM	Search Engine Marketing	Search engine marketing is a form of Internet marketing that involves the promotion of websites by increasing their visibility in search engine results pages through optimization (both on-page and off-page) as well as through advertising (paid placements, contextual advertising, and paid inclusions).
SEO	Search Engine Optimization	SEO is the process of improving the visibility of a website or a web page in search engines' "natural," or un-paid ("organic" or "algorithmic"), search results.

Abbreviation	Description	Definition
	Social Media	Social media is the broad term for internet activities that engage or encourage engagement through online discussions or interactions. E.g.: blogs, microblogs (Twitter), chat rooms, forums, video/photo sharing (YouTube, Flickr), or social networking (Facebook), podcasts, user forums/discussion groups, wikis, news aggregation (RSS), apps etc.
	Social Media Networks	Both the technical networks themselves, such as Facebook, and the networks of connections for individual users. User A is linked to B, C, and D, etc.
UGC	User-Generated Content	Any material that is created by and posted by a user. Examples of user-generated content are: – A “like” rating on an article – A Link rated and forwarded – A comment added into an open text field – A descriptor selected from a list of choices – A photo or other media uploaded
URL	Uniform Resource Locator	The “human-friendly” addresses of resources on the Internet. www.PAAB.ca is a URL

Appendix 1: Overview Tables

Audience	Promotional Claims	Access	PI Disclosure	Preclearance
Schedule Prescription Products, Schedules D Products (excl. vaccines)				
Healthcare Professionals	Yes	Gated	Yes	Yes
Patients	No	Gated	Yes	Yes
Consumers	Yes[1]	Open	No	Yes[2]
Schedule D (Vaccines) and Schedule Ethical Products				
Healthcare Professionals	Yes	Open[5]	Yes	Yes
Patients	Yes	Open[5]	Yes	Yes
Consumers	Yes[3]	Open	Yes	Yes[2]
Unscheduled Healthcare Products (incl. OTC/BTC and NHP)				
Healthcare Professionals	Yes	Open[5]	Yes	Yes
Patients	Yes	Open[5]	No	Yes
Controlled Drugs and Targeted Substances (e.g. narcotics, benzodiazapines…)				
Healthcare Professionals	Yes	Gated	Yes	Yes
Patients	No	Gated	Yes	Yes
Consumers	No[4]	NA	NA	NA

1 Federal regulatory requirements restrict prescription drug advertising to the general public to name, price and quantity for Schedule Prescription products. There should be no link between product and therapeutic use for products indicated to treat schedule A diseases.

2 PAAB provides an advisory service to the industry for consumer advertising/information. Note however that pieces used in an HCP setting (e.g. waiting room in a clinic) should be PAAB reviewed.

3 Schedule A disease preventative claims are allowed. Schedule A treatment claims are not allowed.

4 Promotion of narcotics to the general public is not allowed

5 Requires gating if the site houses content which exceeds consumer regulations (e.g. evidence requirements).

Appendix 2 Examples of Online Social Media Projects

Case #1: DTC Prescription Drug Facebook Page

Element to Consider	Discussion
Description of Project:	A manufacturer of a prescription drug (i.e., Schedule Prescription) to treat Type II diabetes (a Schedule A disease) wants to create a branded Facebook page for patients and consumers. The product is indicated to lower blood glucose in combination with diet, exercise and weight reduction. The page will include several tools that the manufacturer has already created and is already using including: • A hypoglycemia tracker/diary • A description of the potential consequences of diabetes and how to avoid them • The consumer package insert • A rebate coupon towards the purchase of the company's own blood glucose monitor • A "call to action" to prompt consumers to switch from their current medication to the manufacturer's product • The comment section of the Facebook page will allow users to post opinions, links and interact with each other and the manufacturer's personnel
The Intent of the Message:	Advertising and promotion
The Type of Drug:	Prescription and a medical device
The Target Audience:	Consumers
The Nature of the Content:	Static and dynamic
Issues:	**Issue #1: Schedule Prescription Products** As the product is Schedule Prescription and the target audience is the general consumer the Food and Drugs Regulations limit the content of such advertising to name, price and quantity (see Table 1). **Issue #2: Schedule A Diseases** Diabetes is a Schedule A disease therefore the Section 3 restriction of the Food and Drugs Act applies. Consequently, the manufacturer is not able to promote any treatment of a Schedule A disease to the consumer.

Element to Consider	Discussion
Possible Alternatives:	As described, this project is not feasible based on the current drug advertising rules. The manufacturer does have some alternatives as outlined below: **i. A patient site:** By creating a gated site accessible to patients who have received a prescription for the product, the manufacturer can make available certain information; however, this cannot include any advertising (or promotional) material (see Appendix 1, Overview Tables). Acceptable content could include information and tools for a patient to better understand and adhere to their therapy such as the hypoglycemia tracker and package insert). If the drug is not indicated to treat the consequences of the disease, the manufacturer will be limited to the consequence content found in part III of the product monograph. Additionally, that content will need to be presented in a manner reflecting the context and level of emphasis from part III of the product monograph. **ii. A consumer disease-related site:** Another option available is to create a disease management site analogous to a consumer brochure. The content cannot emphasize any one product either directly on the site or via the proximity of external links. A Facebook page would be acceptable however, the manufacturer would need to ensure the appropriate monitoring of any user comments to ensure that the site remains compliant and for any adverse event monitoring (see Section 2, Sponsor Oversight Over Online Activities).

Case #2: Disease Awareness Facebook Page

Element to Consider	Discussion
Description of Project:	A manufacturer of a prescription drug (Schedule Prescription) to treat MS would like to create a Facebook page for consumers. The site will not have any product branding however, the manufacturer's logo will be prominently displayed. The site will be similar to a consumer brochure and will include the following type of content: • An overview of MS including diagnosis, progression and prognosis • An overview of treatment options including drugs and medical procedure under investigation • A section on the sponsor's ongoing clinical trials including subject recruitment information • Useful links that direct the user to external sources such as the national association and the manufacturer's Canadian website • The comment section of the Facebook page will allow users to post opinions, links and interact with each other
The Intent of the Message:	Disease information/awareness
The Type of Drug:	None
The Target Audience:	Consumers
The Nature of the Content:	Static and dynamic
Issues:	**Issue #1: Clinical Trial Subject Recruitment** The information proposed on clinical trial recruitment must observe the Health Canada rules for such advertising and the requirements of the Research Ethics Boards (REBs) of the clinical trial sites. There can be no link between the clinical trial sponsor and recruitment advertising. Additionally, all subject recruitment advertising needs prior REB approval. Consequently, the manufacturer needs to exercise caution in this area.

Case #3: Healthcare Professional Community Space Related to a Disease

Element to Consider	Discussion
Description of Project:	A drug manufacturer specializing in Alzheimer's Disease (AD) wants to create an online space for HCPs to access information and engage in discussions between themselves. The idea for this project arose from multiple requests from HCPs. Apart from the corporate logo there will be no product-specific branding. The site will contain reprints from prominent journals (selected by the manufacturer) as well as some tools the manufacturer has developed (such as a screening evaluation). The medical personnel from the manufacturer have been allowed to participate in the online forums.
The Intent of the Message:	Medical and disease information
The Type of Drug:	Prescription
The Target Audience:	Healthcare professionals
The Nature of the Content:	Static, dynamic and third party
Issues:	**Issue #1: Selection of the Content** As the site is intended for the unobstructed exchange of ideas between HCPs, the manufacturer must exercise caution when selecting the material to avoid the introduction of any bias and to avoid the promotions of their drugs. In other words, the sponsor cannot "cherry pick" content that is favourable to their brands or company. All relevant articles must be presented equally and all copyrights respected. **Issue #2: Gating requirements** As the target audience is HCPs, the sponsor is required to appropriately gate the site (see Appendix 1, Overview tables). **Issue #3: Participation of the sponsor's personnel** It is highly recommended that any personnel receive thorough training prior to engraining in online forums. The site is not intended to promote a drug and those that are engaging with HCPs must ensure that the integrity of the exchange remains intact. Additionally, content will need to the monitored for any content that would render the site branded.