Online Drug Information in Canada

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Executive Summary

The Internet is fast becoming a major source of information on prescription drugs for consumers, patients and healthcare professionals. In particular, there has been a rapid increase in the interest in using Internet social media as an avenue for drug promotion. While online drug advertising is regulated in a similar fashion to other types of advertising mediums in Canada, it has many unique features that raise a number of important questions. This report focuses on five research questions intended to broaden our knowledge about online drug information and advertising in Canada.

Question 1: What drug information are Canadians searching for?
In order to ascertain *where* Canadians are likely finding drug information online, it is necessary to first ascertain *what* information they are seeking. I used data from Google Insights for Search to determine the most frequently searched-for drug names in Canada in 2010. I found that the top 5 drugs searched for in Canada were Viagra, Lyrica, Cialis, Ativan and Cipralex, respectively. Overall, I also found that Canadians were much more likely to search using a drug's brand name compared to its generic name.

Question 2: What websites are most commonly returned by drug searches in Canada?
I analyzed the top 10 search results returned on Google Canada searches for a list of popular brand name drugs. The sites most commonly returned in these searches were health information sites (e.g. drugs.com, 30.5%), industry-sponsored sites (e.g. Lipitor.com, 30.1%) and user-created sites (e.g. Wikipedia, 25.8%). Of all the industry-sponsored pages, around seventy-five percent were from the United States, while Canadian manufacturers sponsored just fourteen percent.

Question 3: What drug information are Canadian manufacturers publishing online? Who are the target audiences for this information?
Of the 1150 sites returned in Google search results, 36 led to sites sponsored by Canadian pharmaceutical companies. Most of these sites (25) were intended for consumers, followed by patients (7), both consumers and patients (2), and healthcare professionals (2). Sites intended for consumers most commonly included Part III of the approved product monograph. Every site directed at patients used the drug identification number (DIN) to limit access. However, I also found that DIN numbers are easily determined using online sources. This indicates that while using the DIN as a password may act as a deterrent, it will not prevent access to patient sites by non-patients.

I also reviewed the web page contents of major Canadian drug companies and tow major medical journals. The product sections on the websites of most Canadian pharmaceutical manufacturers were consistent with regulations and contained the

product monograph (either in full or just part III). However, a number of news releases on these sites contained content that might be considered promotional in nature. Finally, there were several online advertisements in publicly accessible journals for Canadian healthcare professionals that contained information on both name and indication.

Question 4: What Internet Social Media activities are Canadian pharmaceutical companies engaged in? What are they planning? What are the major barriers?

The investigations detailed in the first three questions revealed very little use of Internet social media by Canadian drug manufacturers. To investigate why this is the case, I analyzed the results of an online survey the PAAB conducted of Rx&D member companies. This survey, answered by 18 firms, asked about the use of—and barriers to using—sites such as Facebook, Twitter and YouTube. We found that the most-used social media site was Facebook (just under 40% of responding companies) and no other site had more than 20% of companies on it. The most important barrier identified by companies was their perception that the current regulatory framework is unclear (53%), followed by the limits placed on them by current regulatory restrictions (29%) and the time required to monitor and respond to comments (18%). Other less important factors included the cost of developing a social media presence, the difficulty in measuring success and low expected returns.

Question 5: What guidance is provided about online activities in other countries?

Regulatory and self-governing agencies in both the United Kingdom and Australia have guidelines in place regarding the use of the Internet and social media. In general terms, these guidelines stress that sponsorship of sites should be transparent, that sites include approved prescribing information, and that adverse events should be monitored for and reported.

Recommendations

This review led to the following 17 recommendations for future revisions to the PAAB Code:

Overall Recommendations

1. Given their unique nature, the Advertising/Promotion Systems (APS) currently included in Section 6.5 should be split into three separate sections: (1) Internet Web Site APS, (2) Social media site APS, and (3) Audio, visual, Audio/visual (Av) and Electronic APS.
2. Expand Section 6.5 to include sites directed at consumers and patients.
3. PAAB create decision aids and guidance to facilitate increased knowledge about how Canadian regulations apply online.
4. The wording of Section 6.5 be modified to include all Internet APS, not just those “designed to aid representatives”.
5. PAAB should consider allowing electronic submission of Internet APS through private, password-protected access for reviewers.

Internet Web Site Advertising

Sites directed at consumers

6. Web sites directed at the general public should contain the entire product monograph (or Section 3 of the monograph in it's entirety).
7. Medical journals that are openly accessible should be considered as advertising to the general public.
8. Create specific guidance around news releases that are contained on publicly accessible web pages sponsored by pharmaceutical companies. PAAB might consider either providing or requiring pre-clearance services for the content of news releases that will be accessible to the general public.
9. Revise the current wording in the section on links to other sites (6.5.5) indicating "close proximity" to be less vague.
10. Any brand name reminder sites and patient discussion boards should be required to have details regarding the sponsoring company on every page.

Sites directed at patients

11. Given the ease with which DINs can be obtained, sites should use an alternate method to ensure only actual patients can view patient-oriented sites.

Sites directed at healthcare professionals

12. Sites aimed at providers should have a standard and consistent entry restriction system.

Social Media Advertising

13. The next version of the PAAB code should include specific guidance about how often sites must be monitored for comments that breach current advertising regulations, or implement pre-vetting of user-created content.
14. The updated PAAB Code should contain guidelines on how adverse events are to be monitored for and reported.
15. Social media sites sponsored by pharmaceutical manufacturers should provide a system for submitting adverse event data.
16. Company sponsorship of a social media site should be disclosed on every page of the site. In addition, companies should disclose how long they intend to sponsor the site.
17. Advertising to healthcare professionals and patients using either Twitter or Facebook should not be permitted, as it is not possible to restrict access to these groups on these mediums.

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Introduction

In greater numbers and greater frequency, patients are turning to the Internet for information about their medicines. For example, more than one third of all US residents looked to the Internet for information on prescription drugs in 2008.[1] While we lack comparable numbers for Canada, it is likely that Canadians are seeking drug information in similar numbers. Further, as younger individuals are more likely to use the Internet as a source of information, the use of online drug information is poised to grow even further in the future.

At the same time, spending on Internet advertising by pharmaceutical manufacturers has also increased. In the United States, expenditure on online advertising now represents 5% of total spending.[2] While this is small compared to the overall spending on other media such as television and print media, these other sources may lead patients to search online for further information about a therapy. I could find no public data on the current rates of Internet advertising expenditure by Canadian companies. However, if the use of online advertising by Canadian manufacturers is increasing at a similar rate, it is vital that regulation of online drug advertising keep pace with the rapid developments in this space.

Online communications also raise a number of unique issues regarding pharmaceutical advertising to physicians, patients and consumers. While Canadian regulations allow pharmaceutical companies to communicate information on name, price and quantity to consumers (without discussing clinical indications), communications to both existing patients and physicians are regulated in a different fashion. Advertising online by Canadian pharmaceutical companies is subject to similar regulations as existing print and television advertising. Social media also raises important new questions about how companies monitor sites, how adverse events should be reported and what systems are necessary to limit access to the intended audience. All of these are areas of ongoing change and development.

Further, the Internet does not obey national and professional boundaries in the same fashion as print information did in the past. While the current Canadian regulations allow online advertising by Canadian companies under similar laws to those that apply to print advertising, these rules differ in many other countries. As with television advertising, there is likely much cross-border exposure to advertising from other countries. We know from research on television that American DTCA has the potential to influence Canadian prescribing, at least in the short-term.[3] While there may be limited regulatory avenues to restrict access to international materials on pharmaceuticals, it is nevertheless important for regulators to be aware of what information Canadians are possibly accessing.

In order to develop appropriate regulatory responses, we require information on what activities are currently being undertaken. Despite this need, we have only

limited information on what web sites Canadians likely find in online searches for drug information. For instance, a recent study I authored investigated search engine results in Canada, and found the first result often led to American drug company websites.[3] However, beyond the first result we have little information about the rest of the search results Canadians find, the information on the drugs they are searching for and the content of Canadian pharmaceutical company websites.

Report Overview

This report outlines a series of research investigations that attempt to answer a series of key questions about the online advertising space for pharmaceuticals in Canada. This report investigates 5 separate questions, including:

1. What drug information are Canadians searching for? How are they searching for it?
2. What websites are most commonly returned by drug searches in Canada?
3. What drug information are Canadian manufacturers publishing online? Who are the target audiences for this information?
4. What Internet Social Media activities are Canadian pharmaceutical companies engaged in? What are they planning? What are the major barriers?
5. What guidance is provided about online activities in other countries?

This report will turn to each of these questions in turn following a brief section outlining the context of drug information searches in Canada. The report then concludes with a series of recommendations for updating the PAAB Code based on my findings.

Setting the Context: The volume of drug information searches performed in Canada

Search Trends

In order to believe that online drug information is increasingly important to consider in the regulatory framework for drug advertising, we must demonstrate that they are an increasingly active component of health-seeking behavior by Canadians. This appears to be the case. Recently, we know from Statistics Canada research that 70% of Canadian Internet users searched for medical or health-related information in 2009, an increase from 59% in 2007.[4] Unfortunately, this data source does not provide information on drug-specific searches.

In order to investigate the trend in online searches for drug information by Canadians, I compiled the weekly search trends for related search terms using Google Insights for Search. This online service allows researchers to investigate the geographic trend in use of particular search terms. I focused on the subcategory of "Drugs and Medications" within the category "Health". Figure 1 shows the weekly

change in search trend relative to all searches performed in Canada using Google from January 2008 through December 2010. This chart represents the growth in the number of searches that fall within the category of "Drugs and Medications" relative to the total number of searches conducted in Canada using Google during the period. As shown in the chart, since 2009 this category has constituted a growing proportion of the overall number of searches on Google. As the overall number of searches has also been increasing, this indicates that Canadians are using the Internet with increasing frequency to search for drug information.

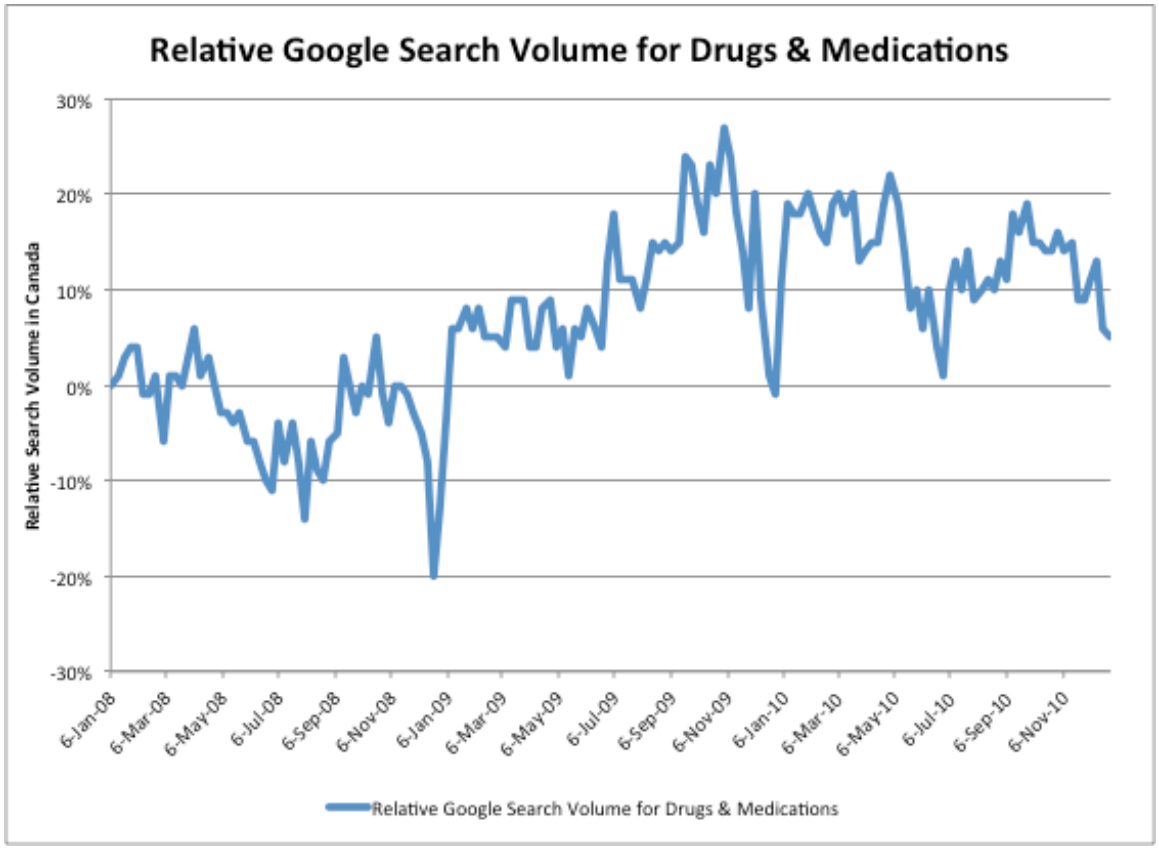

Figure 1. Relative weekly search volume for drugs and medications in Canada, 2008-2010 (Source: Google Insights for Search)

Volume of DTCA Spending in Canada

Unfortunately, the most recent data we have on DTCA spending by Canadian pharmaceutical companies comes from 2006.[5] However, over the timeframe of 1995 to 2006, there was an increase in DTCA spending by Canadian companies, from approximately $10 million to $37 million. This increase in spending may have resulted in more use of the Internet as consumers look for information on the products they see advertised. It is worth noting that over one quarter (26%) of spending in Canada was concentrated on one product (Viagra), and the top 5 brands represented 68% of total spending. This suggests that both the overall number and total budget of spending on DTCA remain very small compared to the United States in both total and per-capita terms. Unfortunately, I could find no recent information on Internet advertising spending by Canadian pharmaceutical manufacturers.

Research Question 1: What drug information are Canadians searching for? How are they searching for it?

In order to ascertain *where* Canadians are likely finding drug information online, it is necessary to first ascertain *what* information they are seeking. This section of the report proceeds in two steps: first, I develop a list of drugs that are likely to be searched for by Canadian audiences. Second, I use Google's Insights for Search system to determine the relative frequency of searches for different drug-related terms. This results in a rank-ordered list of drugs for which Canadians are seeking information online.

My use of Google search engine volumes to approximate actual Internet information-seeking patterns in Canada is well justified. We know from prior research that most information gathering by individuals uses a search engine rather than a health portal or other information site: 92% of Americans use a search engine to fine information on the web.[6] Moreover, Canadian web searches are overwhelmingly (91%) performed using Google.[7]

Research Methods

Data

Drug Names

To compile a list of likely drug-related search terms being used by Canadians, I combined data from 3 different sources:

1. First, I used a list of the top 50 most-prescribed drugs in Canada produced by IMS Brogan.[8] This list contained both branded and generic medications ranked by the number of prescriptions dispensed in 2010. This list contained 27 brand name drugs and 23 generic drugs. For conducting search volume estimates, I combined the records for generic ingredients that were duplicated from different manufacturers (e.g. metformin, metoprolol). After these modifications, 45 drugs from this group were included in my sample (26 brand name and 19 generic drugs).

2. Second, as some drugs that are highly advertised will not be as widely prescribed as the top 50 list, I also added all drugs available in Canada that were amongst the top 25 most advertised to consumers in the USA.[9] I chose to use this list for two reasons. First, we know from prior research that Canadian prescribing can be influenced by cross-border advertising exposure.[3] Second, at least some of the drugs that were highly advertised in the US in 2010 have also been advertised in Canada (e.g. Viagra, Celebrex).[5] This resulted in 14 additional brand-name drugs being added to the sample. Unfortunately, the most recent public data available on DTCA expenditures in Canada are from 2006 and are likely not applicable today.[5]

3. Third, I compiled a list of the top 20 drug name searches conducted on Google in 2010 in Canada using the category "Drugs and Medications" on Google Insights for Search. I excluded OTC products and non-specific search terms (e.g. "medication"). This added an additional 8 products to the sample, including 6 brand names and 2 generics.

In total, this led to a complete sample of 67 drugs, including 48 brand name drugs. For brands, I matched with brand name with the generic drug name using the Health Canada Drug Product Database.[10] Generic names were shortened to the first word (e.g. "atorvastatin calcium" to "atorvastatin"), as were brand names that were listed as extended release versions (e.g. "Adalat XL" to "Adalat").

Search Volumes

To investigate the characteristics of what drug information Canadians are searching for online, I used data from Google Insights for Search. Google Insights for search provides relative search volumes for search terms or categories with three possible restrictions: time (e.g. 2010), region (e.g. Canada) and category (e.g. "Drugs and Medications"). Within these groupings, one can compare one or more search term to study the relative search volume between the two terms.

As Google Insights for search only provides relative search volumes and not the absolute number of searches conducted, I chose to use the search volume for the most dispensed drug in Canada (Synthroid) as the benchmark. Thus, the data for each brand name and generic name search are reported relative to the search volume for Synthroid. Thus, if a drug had a search volume measure of 110%, it indicates that it was searched more 10% more frequently than Synthroid.

Analysis

Using the relative search data obtained for each brand name and each generic name, I assembled a table to rank-order drug-related search terms in order of frequency with which they were searched on Google in Canada in 2010. Further, in order to compare the frequency of brand name versus generic name searches, I calculated the ratio of brand name to generic name searches for the 46 brand name drugs in the sample. This statistics represents the number of brand name searches that were conducted for each generic name search. For example, a ratio of 5.0 would indicate that the brand name was searched for 5 times more often than the generic name.

Results

The top 25 most searched for brand names from our sample, and their relative search volume compared to Synthroid, are shown in Table 1. Notably, two of the top 3 medicines were treatments for erectile dysfunction (Viagra and Cialis, respectively) and the second most-frequently searched for medicine was a treatment for neuropathic pain and fibromyalgia (Lyrica). A number of other classes feature prominently in the list, including antidepressants, benzodiazepines, narcotics, birth control and cardiovascular treatments.

Brand Name	Generic Name	Brand Search Volume in 2010 vs. Synthroid
Viagra	sildenafil	307%
Lyrica	pregabalin	187%
Cialis	tadalafil	186%
Ativan	lorazepam	170%
Cipralex	escitalopram	169%
Xanax	alprazolam	164%
Effexor	venlafaxine	164%
Percocet	oxycodone	158%
Lipitor	atorvastatin	154%
Yasmin	drospirenone	150%
Celebrex	celecoxib	147%
Seroquel	quetiapine	145%
Wellbutrin	bupropion	144%
Prozac	fluoxetine	142%
Celexa	citalopram	140%
Cymbalta	duloxetine	138%
Crestor	rosuvastatin	130%
Zoloft	sertraline	121%
Nexium	esomeprazole	116%
Paxil	paroxetine	110%
Synthroid	levothyroxine	100%
Coumadin	warfarin	89%
Plavix	clopidogrel	87%
Champix	varenicline	83%
Alesse	estradiol	78%

Table 1. Top 25 Brand Name drug searches in Canada in 2010 (Source: Author's calculations based on data from Google Insights for Search)

The top generic drug searches are shown in Table 2. As seen in the table, some of the top brand name searches also appear in the generic search term list (e.g. oxycodone).

Comparing the search volumes for the brand name versus generic name indicates that the brand name is overwhelmingly used in online drug searches in Canada. Of the 46 brand name drugs I studied, there were only 3 instances where the generic name was used more frequently (warfarin, levothyroxine and codeine). Overall, the ratio of brand to generic searches was greater than 5, suggesting the brand name is used at least five times more frequently than the generic name to search for drug information online.

Research Question 2: What websites are most commonly returned by drug searches in Canada?

The background research and results from the background section suggest that Canadians are increasingly using the Internet to search for drug information. Given this trend, it is important to discern the type and source of the information that they are finding as a result. In prior work, I found that the top hit for Google searches initiated in Canada was often Wikipedia or sites run by American pharmaceutical manufacturers.[11] However, as click-through on the first site is not guaranteed, this section expands on my prior work to consider the top 10 results for all the drug names determined in Question 1. In this section of the report, I studied the top 10

Brand Name	Generic Name	Generic Search Volume in 2010 vs. Synthroid
	Prednisone	191%
	Naproxen	172%
Tylenol with Codeine	Codeine	158%
Percocet	Oxycodone	154%
	Tramadol	140%
	Metformin	139%
	Amoxicillin	135%
	Clonazepam	134%
Celexa	Citalopram	132%
	Acetaminophen	130%
Ativan	Lorazepam	120%
Coumadin	Warfarin	99%
	Metoprolol	87%
	Hydrocodone	84%
	Ramipril	84%
Effexor	Venlafaxine	81%
	Hydrocholorothiazide	66%
	Pantoprazole	65%
Zoloft	Sertraline	63%
Seroquel	Quetiapine	62%
	Rabeprazole	57%
Prozac	Fluoxetine	47%
Ventolin	Salbutamol	47%
Wellbutrin	Bupropion	47%
Xanax	Alprazolam	46%

Table 2. Top 25 generic drug names searches in Canada in 2010 (Source: Author's calculations based on data from Google Insights for Search)

results from Google search results in Canada for each drug and classified the sites into categories.

Data

Drug names

I used all of the 67 drugs revealed through my three sources in Section 1 (n=48 brand name drugs and n=19 generic drugs). I included the generic name of all brand name medicines in the list for my searches (e.g. atorvastatin).

Web Site

For each drug, I collected the top 10 results from Google.ca. All searches were conducted with a clean browser cache and with a browser not logged into a Google Account to restrict the use of personalized search history in informing the results. Overall, this led to a sample of 1150 search results, including 480 resulting web

links for brand names and 670 for the generic names. Following collection, I aggregated by web site (e.g. en.wikipedia.org) and manually classified each of the sites as being from industry, or from another category (e.g. user-created, health information site, research organization, association, online pharmacy, other). For industry and health information sites, I also ascertained the country of origin of the site, based on the text of the lead page, or the linked "about us" or "contact us" pages.

Weighting

To summarize the national origin and source of the pages returned by Google searches conducted in Canada, I used a two-stage weighting process. First, I weighted each brand and generic name by the relative search volume reported in the results of Question 1. This would mean that a page returned at the same position for the brand name search "Yasmin" was weighted 150% higher than a search for "Synthroid". This makes my resulting estimates more representative of the overall page types Canadians are receiving in their search results. Second, I weighted each individual site based on the position it appeared in the Google results. Prior research has indicated that search ranking is a very important determinant of whether an individual ultimately clicks through on a result. As shown in Table 3, page traffic is heavily dependent on Google search ranking.[12]

Google Result	Click-through rate
1	34.4%
2	17.0%
3	11.4%
4	7.7%
5	6.2%
6	5.1%
7	4.0%
8	3.5%
9	2.9%
10	2.7%
11 and higher	5.3%

Table 3. Click-through traffic based on Google search result ranking

While these estimates are for the United States, I could find no comparable statistics for Canada. However, there is little reason to believe they substantially differ, as Google is similar in function and appearance between the two countries.

The resulting figures presented below are all presented as percentages of the final "search result weight" that takes into account both weighting variables. In essence, they represent the estimated percentage with which a Canadian search on Google would lead to a particular type of web page, accounting for both the frequency with which individual drug names are searched and the frequency with which differently-ranked search results are typically chosen by those who conduct online searches.

Analysis

Based on the weighted search result figures, I compiled three tables of statistics for each of the brand name searches and generic name searches I conducted:

1. First, I calculated the weighted percentage of search volume that links to specific websites (e.g. wikipedia.ca). This gives an overall sense of the major websites that are consistently returned across different drug names.
2. Second, I tabled the country of origin for the websites returned. For this table, I excluded all sites that were blogs, discussion boards or online pharmacies.
3. Third, I determined the weighted percentage of search results that were sourced from each type of website (e.g. industry). I also subdivided this table into national origin.

Results

Top sites

As shown in Table 4, the top sites returned for brand name searches are heavily concentrated on a few particular websites. For example, the user-generated site Wikipedia accounts for nearly one-quarter of all the weighted search results returned in Canadian Google searches. Two Canada-specific health information sites also appear in the top 10 results (Canoe.ca and Canada.com). Finally, a series of Industry sites from the US round out the top 10, as they are the first result listed for some drugs that have a very high search volume.

Website	Site Type	Search Result Weight
en.wikipedia.org	User-generated	24.41%
drugs.com	Health Information (NZ)	8.03%
chealth.canoe.ca	Health Information (Canada)	5.44%
bodyandhealth.canada.com	Health Information (Canada)	3.42%
medicinenet.com	Health Information (USA)	3.32%
medbroadcast.com	Health Information (USA)	3.20%
rxlist.com	Health Information (USA)	2.54%
viagra.com	Industry (USA)	2.44%
lipitor.com	Industry (USA)	1.82%
crestor.com	Industry (USA)	1.54%

Table 4. Top 10 websites returned in Canadian searches for brand names, by search weight (source: Author's calculations based on data from Google.ca)

As shown in Table 5, Wikipedia also was the most highly weighted individual site in Canadian Google searches for generic drug names, with 36% of the total search weight. As with the overall brand name results, a number of health information sites also appeared in the results, as did two government sites (one from the US and one from Canada).

Website	Site Type	Search Result Weight
en.wikipedia.org	User-generated	36.40%
medicinenet.com	Health Information (USA)	16.96%
drugs.com	Health Information (NZ)	8.07%
nlm.nih.gov	Government (USA)	6.38%
chealth.canoe.ca	Health Information (Canada)	5.73%
bodyandhealth.canada.com	Health Information (Canada)	2.43%
rxlist.com	Health Information (USA)	1.94%
medbroadcast.com	Health Information (USA)	1.75%
drugbank.ca	Research Org. (Canada)	1.46%
hc-sc.gc.ca	Government (Canada)	1.35%

Table 5. Top 10 websites returned in Canadian searches for generic names, by search weight (source: Author's calculations based on data from Google.ca)

Country of Origin

Table 6 shows the country of origin for Google searches conducted in Canada for the brand names of the sample of drugs. There were sites from three major regions represented in the results: the United States (31%), International (28%, largely wikipedia.org) and Canada (22%). Many search results led to blogs, online pharmacies or discussion boards, so were not attributed to a single region. Finally, the New Zealand constituted 8% of the search result weight, largely due to the health information site drugs.com.

Table 7 shows that the results for Canadian Google searches of generic drug names were only marginally different from brands. The share of the search weight held by international sites was higher at 37%, the US was nearly identical at 32% and the share of sites from Canada was lower at 15%.

Both of these analyses suggest that a significant majority of sites returned

Country of Origin	Search Result Weight
USA	30.94%
International	28.48%
Canada	21.68%
N/A	9.09%
New Zealand	8.06%
United Kingdom	1.30%
Unknown	0.35%
Jordan	0.10%

Table 6. Country of Origin for Brand Name medicine searches on Google in Canada, by search result weight (source: Author's calculations based on data from Google.ca)

Country of Origin	Search Result Weight
International	36.98%
USA	31.78%
Canada	14.69%
New Zealand	8.08%
N/A	5.25%
Unknown	1.50%
United Kingdom	1.34%
Australia	0.26%
Bulgaria	0.10%
Europe	0.00%

Table 7. Country of Origin for Generic Name medicine searches on Google in Canada, by search result weight (source: Author's calculations based on data from Google.ca)

in Google searches conducted in Canada are not leading to Canadian websites. Thus, it appears that much of the content Canadians will retrieve online will not be subject to national regulations on pharmaceutical advertising.

Source

Perhaps most important from the standpoint of the Canadian regulatory development is the source of drug information that is being returned in Canada-based searches for drug information. Table 8 shows the search result weight for each different type of site identified in all the websites returned. As shown in the table, only three types of sites dominated the search results: Health Information sites (e.g. drugs.com), Industry-sponsored pages (e.g. Lipitor.ca) and user-created sites (e.g. Wikipedia). While online pharmacies have nearly 5% of the search weight, no other type of site garnered more than 2% of the brand search weight.

Site Type	Search Result Weight
Health Information	30.51%
Industry	30.06%
User-created	25.84%
Online Pharmacy	4.77%
Blog	2.22%
Other	1.72%
News	1.66%
Government	1.62%
Lawyer	0.44%
Association	0.43%
Discussion Board	0.39%
Research Organization	0.23%
Journal	0.13%

Table 8. Site sponsor type for Brand Name medicine searches on Google in Canada, by search result weight (source: Author's calculations based on data from Google.ca)

Country	Search Result Weight
Canada	43.15%
New Zealand	26.32%
USA	26.20%
United Kingdom	3.19%
Unknown	1.14%

Table 9. Country of Origin for Brand Name medicine search results that led to a Health Information site on Google in Canada, by search result weight (source: Author's calculations based on data from Google.ca)

To investigate the national source of the two largest sponsor types for brand drug name searches, I broke down both Health Information sites and Industry sponsored sites into their national source in Table 9 and Table 10, respectively. While the largest source of Health Information sites is Canada, the USA accounts for over 75% of the industry-sponsored sites returned in Google searches conducted in Canada. Canadian sites represented just 15%. When considered as a whole, Canadian pharmaceutical companies are responsible for less than 5% of the total search weight returned in brand name searches on Google in Canada. This suggests that

Country	Search Result Weight
USA	75.50%
Canada	14.73%
International	8.78%
United Kingdom	0.65%
Jordan	0.33%

Table 10. Country of Origin for Brand Name medicine search results that led to an Industry-sponsored site on Google in Canada, by search result weight (source: Author's calculations based on data from Google.ca)

they are likely not a major source that Canadians will visit after a Google search for a specific brand name medicine.

In terms of searches on the generic drug name, Table 11 shows that Health Information sites (e.g. drugs.com) and user-created sites represent the two largest shares of the resulting search result weight. In contrast, Industry-sponsored sites represent less than 1% of the total search weight, indicating there is a very low likelihood that a Canadian searching for a generic drug name will visit an Industry-sponsored website.

Site Type	Search Result Weight
Health Information	44.17%
User-created	36.98%
Government	9.29%
Online Pharmacy	3.08%
Research Organization	1.96%
Other	1.40%
News	0.79%
Industry	0.61%
Discussion Group	0.57%
Journal	0.48%
Association	0.30%
Blog	0.25%
Healthcare Provider	0.14%

Table 11. Site sponsor, generic name searches (source: Author's calculations based on data from Google.ca)

Research Question 3: What drug information are Canadian manufacturers publishing online? Who are the target audiences for this information?

The results from Section 2 of this report indicate that Canadian pharmaceutical manufacturers do have a presence online, albeit a relatively minor one that is limited largely to searches based on the brand name. The information identified includes areas of online activity that fall within the current scope of the PAAB Code (e.g. sites aimed at healthcare professionals), as well as areas that are not within the current scope of the PAAB Code (e.g. websites directed at consumers and general news releases).

To investigate the drug information that Canadian manufacturers are publishing online, I investigated the search results from the second question that linked to Canadian industry websites, along with the corporate web pages of some major Canadian manufacturers. This review included a specific focus on the product information and news release segments of the websites. The focus of these reviews was to document the content of the pages, the target audience and any page restrictions that are in place. Finally, I reviewed a sample of advertisements in two of the most prominent online Canadian medical journals.

Analysis of Search Engine Results

Methods

I used the search engine results from Question 2 to determine the major websites that fall under PAAB jurisdiction that consumers would find in popular search engine queries. In total, of the 1150 search results for both brand and generic medicines, just 36 of them led to a Canadian Industry-sponsored website. Of these sites, 30 were returned in searches on the brand name, while 6 were returned on searches for the generic name. On these sites, I also observed whether the PAAB Logo was present. However, it should be noted that displaying the logo is not required on sites that have been reviewed.

Results

The details of the 36 websites are shown in Table 12. As shown in the table, only 2 industry-sponsored websites were the first-ranking result for searches on either the brand or generic name, and only 1 further site ranked in the top 3. The main audience for the sites was consumers (25 sites), followed by patients (7 sites), healthcare professionals (2 sites) and sites directed at both consumers and patients (2 sites). The sites contained a range of information, most commonly all or part III of the corresponding product monograph. Of the sites directed at patients, all used the product DIN as a password for entry to the site, suggesting it has emerged as the standard method for restricting access to patient-directed sites. Only 2 of these sites displayed the PAAB logo.

Keyword	Rank	Website	Company	Audience	Content	Restriction Method	PAAB Logo
Abilify	7	bmscanada.ca	BMS	Consumers	Part III	-	No
Advair	6	advair.ca	GSK	Patients	Patient info, Drug Info, Patient Reminders	DIN	No
Advair	7	gsk.ca	GSK	Consumers	Product Monograph, How-to-use videos	-	No
Alesse	1	alesse.ca	Pfizer	Patients	Patient FAQ, Drug Info, Sexual Health Info	DIN	No
Alesse	7	startsomethingwithalesse.ca	Pfizer	Consumers	Contest	-	No
Atacand	7	astrazeneca.ca	AstraZeneca	Consumers	Part III (pdf)	-	No
Atacand	8	astrazeneca.ca	AstraZeneca	Consumers	Monograph (full)	-	No
Avapro	6	bmscanada.ca	BMS	Consumers	Part III	-	No
Avapro	8	products.sanofi.ca	Sanofi	Consumers	Monograph (full)	-	No
Celebrex	7	celebrex.ca	Pfizer	Both	Name, Recipes, Lifestyle tips	DIN	No
Champix	3	champix.com	Not on page	Both	Ad, Doctor questions, patient program	DIN	No
Champix	8	pfizer.ca	Pfizer	Consumers	Monograph (both parts), safety information	-	No
Coversyl	8	servier.ca	Servier	Consumers	Monograph (full)	-	No

Keyword	Rank	Website	Company	Audience	Content	Restriction Method	PAAB Logo
Crestor	8	crestor.ca	AstraZeneca	Healthcare Professionals	Name, Indication, Tracking tools	None	No
Enbrel	10	enbrel.ca	Amgen	Patients	Use, Disease Information, Patient support program	DIN	No
Ezetrol	7	merckfrosst.ca	Merck	Consumers	Monograph (both parts)	-	No
Flovent	4	gsk.ca	GSK	Consumers	Monograph (both parts), safety information	-	No
Januvia	7	merckfrosst.ca	Merck	Consumers	News release (includes name and indication)	-	No
Januvia	10	merckfrosst.ca	Merck	Consumers	Monograph (both parts)	-	No
Lyrica	5	pfizer.ca	Pfizer	Consumers	Monograph (both parts)	-	No
Nexium	5	nexium.ca	AstraZeneca	Patients	Patient info, Drug Info	DIN	Yes
Plavix	5	bmscanada.ca	BMS	Consumers	Part III	-	No
Singulair	4	merckfrosst.ca	Merck	Consumers	History of drug, name and indication	-	No
Symbicort	4	astrazeneca.ca	AstraZeneca	Consumers	Part III (pdf)	-	No
Symbicort	8	symbicort.ca	AstraZeneca	Patients	Patient info, Drug Info	DIN	No
Synthroid	8	abbott.ca	Abbott	Consumers	Monograph (both parts)	-	No
Tylenol with Codeine	9	janssen-ortho.com	Janssen-Ortho	Healthcare Professionals	Prescribing information (not a monograph)	-	No
Viagra	4	viagra.ca	Pfizer	Both	Ads, Doctor Aid; Patient and Disease Info	DIN	No
Vyvanse	10	vyvanse.ca	Shire	Patients	Reminders, Tracking	DIN	No
Yasmin	1	yasmin.ca	Not on page (Bayer)	Patients	Patient Info	DIN	Yes
Bisoprolol	6	sandoz.ca	Sandoz	Consumers	Prescribing information (not the monograph)	-	No
Candesartan Cilexetil	9	astrazeneca.ca	AstraZeneca	Consumers	Monograph (full)	-	
Monteleukast	6	merckfrosst.ca	Merck-Frosst	Consumers	Name, Indication, History	-	No
Pantoprazole	7	ranbaxy.ca	Ranbaxy	Consumers	Product Listing	-	No
Risedronate	4	products.sanofi.ca	Sanofi-Aventis	Consumers	Monograph (full)	-	No
Sitagliptin	5	merckfrosst.ca	Merck-Frosst	Consumers	News release (includes name and indication)	-	No

Table 12. Characteristics of top-ranking pages from Canadian Industry Sources

Notable Canadian Sites

Some sites that were identified are notable for certain aspects of their content, including:

1. The 8th page result for searches on "Crestor" leads to the Crestor site intended for patients, with a message "Welcome, Healthcare Professional" on the main page. There is no entry restriction on this site. (the site was available at http://www.crestor.ca/doctors.aspx)
2. The 4th page result for "Singulair" led to a page on the history of the drug on Merck Frosst's Canadian website that includes information on both the name and indication of the drug (http://www.merckfrosst.ca/mfcl/en/corporate/research/accomplishments/singulair.html)
3. The number 3 result for "Champix" leads to an information page that does not include the name of the sponsoring company. (http://champix.com). This would appear to contravene PAAB Code section 6.5.2.
4. The number 5 results for "Sitagliptin" leads to a news release on the Merck website that lists both name and indication. (http://www.merckfrosst.ca/assets/en/pdf/press/r_d_news/diabetes/press_releases/ADA_Release_Eng_June_13_FINAL_dh.pdf)

Notable International sites

Of the highly ranked industry-sponsored sites not located in Canada, Adalat.com was notable for its content. The site describes itself as being "intended to provide information to an international audience outside the USA and UK". However, the site contains information on name and indication in the section of the site intended for individuals that are not healthcare professionals.

Further, many of the US industry-sponsored sites say they are "intended for use by U.S. residents", but it is often in small text at the bottom of the page. Often on these sites there is also a link to the Health-care Professional site that does not require any form of login (for example, on www.plavix.com). While these sites are clearly out of PAAB's jurisdiction, it makes it all the more important that high-quality information that meets Canadian guidelines is available online.

Use of Keywords

Section 6.5.3 of the PAAB code stipulates that "sponsors should not provide the text of a meta data descriptor that contains direct or implied product claims to a search engine." To ensure this is the case, I examined the meta data for every top page sponsored by Canadian industry. The meta keywords (invisible keywords visible to search engines) for none of the pages included any information on the clinical indication for the medicine, or the name of competitors. This indicates that this section of the code is being followed in sites that Canadians might regularly visit.

Extension: The strength of the DIN as a restriction method

Given the above results indicating the sites that include patient information are exclusively using the DIN as a password, I investigated the security of this method. To do this, I entered the brand name and DIN into a Google Search (e.g. "Advair DIN"), to see if a member of the general public could easily find the DIN. Alternative

sources of the DIN, such as the Health Canada Drug Product Database were not used, as I suspect they would be difficult to find and use for the general public.

The results of this search indicate that the DIN is readily available and simple to find. For example, the first search for "Advair DIN" leads to the Canada.com drug information page for Advair , which clearly shows the DIN for several different dosage forms (http://bodyandhealth.canada.com/drug_info_details.asp?brand_name_id=3495). Similar results appear in the searches for every other drug. In fact, the DIN can be obtained from the first search result for 9 of the 10 brand names identified, and is on the second search result for the remaining drug.

For many drugs, obtaining the DIN in this method doesn't even require a click-through to another page. For example, a Google search for "Champix DIN" gives the results shown in Figure 2, which clearly shows two DIN numbers in the page summary.

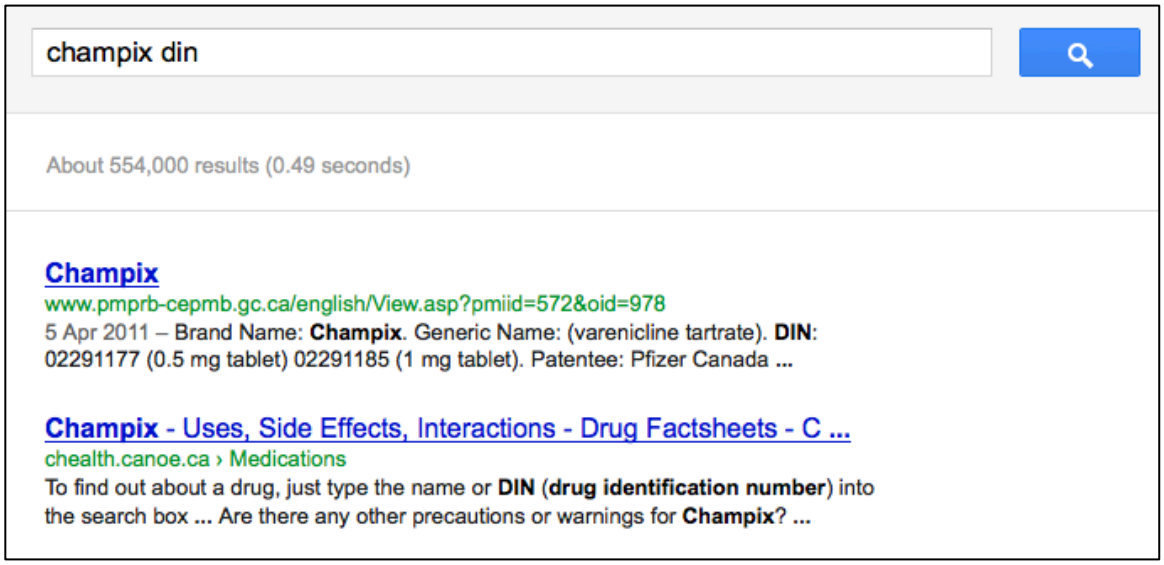

Figure 2. Google search results for a search using "Champix DIN"

Top Pharmaceutical Company Sites

Methods

To investigate the content on the top pharmaceutical company websites in Canada, I studied the websites of all companies that appeared on the IMS Brogan Top 10 Pharmaceutical Corporations in Canada list in either 2009 or 2010.[13,14] Sites were examined to view what information is currently available. Companies that had been part of merger activity (Schering-Plough and Wyeth) were not considered as their corporate websites are now closed and redirected to the new parent company site.

Particular attention was devoted to media releases that were present on corporate websites. Health Canada stipulates that media releases are only considered not to be promotional under the following circumstances (partial list)[15]:

1. The announcement is directed to shareholders
2. No statement is made regarding the degree of safety or efficacy expected
3. No comparison is drawn with other treatments

Therefore, all releases were compared with these criteria in my evaluation.

Results

As shown in Table 13, my criteria for inclusion resulted in 11 websites being analyzed. I found that the product information pages on the sites showed a remarkable consistency, with every company displaying the approved product monograph for their products. However, there were some differences in the media releases section of the sites. Notably, there were several instances where pages could be considered to have "promotional" content based on the above criteria from Health Canada.

Company	Site	Main Drug Page Content	Press Release Content
AstraZeneca	astrazeneca.ca	Product Monographs	Some contain claims of safety and efficacy (http://www.astrazeneca.ca/en/news/release.asp?id=2011091201), comparison to other treatments (http://www.astrazeneca.ca/en/news/release.asp?id=2011060101)
Abbott	abbott.ca	Product Monographs	One contains claims of "remarkable" efficacy (http://www.abbott.ca/static/cms_workspace/en_CA/content/document/humira-jan24-08-en.pdf)
Apotex	apotex.com	Product Monographs	Largely product approval information
Bristol-Myers Squibb	bmscanada.ca	Product Monographs	Some contain claims regarding efficacy (http://www.bmscanada.ca/en/news/release/health-canada-s-approval-of-an-expanded-indication-for-plavix-r-clopidogrel-bisulfate-now-offers-pro)
GlaxoSmithKline	gsk.ca	Product Monographs	Some make claims regarding safety (http://www.gsk.ca/english/docs-pdf/JAMA_FNL_ENG_09122007.pdf)
Janssen-Ortho	janssen-ortho.com	Product Monographs, DIN-protected patient site	Predominantly safety updates
Merck Frosst	merck.ca	Product Monographs	Some make claims regarding efficacy (http://merck.ca/newsroom/ca_en/product-news/VICTRELIS_IDSA_Coinfection_Data_release_Oct_20_2011_EN.pdf)
Novartis	novartis.ca	Product Monographs, Safety Updates	Some make claims regarding efficacy (http://www.novartis.ca/downloads/en/News/Gilenya_Release_Mar2011_eng.pdf)
Pfizer	pfizer.ca	Product Monographs	Some contain safety claims (http://www.pfizer.ca/en/media_centre/news_releases/article?year=2009&article=307)
Roche	rochecanada.com	Product Monographs	Some contain efficacy claims (http://www.rochecanada.com/portal/ca/media_releases?siteUuid=re7234008&paf_gear_id=45200037&pageId=re7540115&synergyaction=show&paf_dm=full&nodeId=1415-0f6ca2108dec11df8f05f52e79bc3a2f&currentPage=0)
Teva	tevacanada.com	Link to DPD, Registration required HCP site	None, just a contact email address.

Table 13. The drug information on major pharmaceutical company websites

For example, one media release on the Abbott site contained claims about "remarkable" efficacy on a media release containing information on both product name and indication that was not explicitly directed to shareholders

(http://www.abbott.ca/static/cms_workspace/en_CA/content/document/humira-jan24-08-en.pdf). Some other examples of efficacy and safety claims are shown in the table. Of note, there were also many comparisons to alternative treatments (in particular comparisons to the existing standard of care).

Summary

In summary, this review indicates that the drug information component of Canadian pharmaceutical company websites revolve largely around providing the information available in the product monograph. However, my review of the news releases component of these same websites found some potentially problematic information that PAAB should consider specifically addressing in future code revisions.

Major Journals for Health Professionals

Methods

For this review, I periodically examined the banner advertisements that appeared on two major Canadian journals intended for physicians, the CMAJ and Canadian Family Physician in the latter half of 2011. Both journals include banner advertisements at the top of every page and there were several instances of drug advertising. Below, I have categorized these advertisements into 5 different types. Further, the current PAAB code (section 6.5.4) indicates notes that banner advertisements: "Must be page-linked to the prescribing information". I assessed whether or not this was the case.

Results

I found significant variation in the types and click-through sites of advertisements in the publicly accessible pages on these two medical journal sites. Only Type 1 conforms to the current PAAB code that requires page links to the prescribing information, while the other types click-through to other content. However, as the site it appeared on is accessible to the general public, even this type of advertising would appear to contravene Canadian regulations about advertising to consumers.

Type 1: Name-only advertisement with click-through to product monograph

Figure 3. Online journal advertisement for Brilinta

Figure 3 shows an advertisement for Brilinta that appeared in an online journal. It contains only the drug name and the click-through leads to the full product monograph, as stipulated in the PAAB Code. However, as this is a publicly accessible site, this link appears to contravene Canadian restrictions on DTCA.

Type 2: Name and indication advertisement with click-through to pdf advertisement

Figure 4. Journal advertisement for Zuacta

Figure 4 shows an advertisement for Zuacta that appeared in an online journal that contains both the drug name and indication. This advertisement displays the PAAB logo. However, it contains both drug name and indication information on a publicly accessible page. Further, the click-through led to a publicly accessible advertisement (in pdf format) aimed at physicians that contained name, indication, and both safety and efficacy claims regarding the medicine.

Type 3: Name-only advertisement with generic information page

Figure 5. Online journal advertisement for Vimovo

Figure 5 shows an advertisement for Vimovo. This advertisement contains only name information, and clicks through to a PDF that encourages physicians to consult the campaign material in "CMAJ and other major medical publications" (See Figure 6 below). This type of advertising would appear to be consistent with current regulations on advertising to consumers.

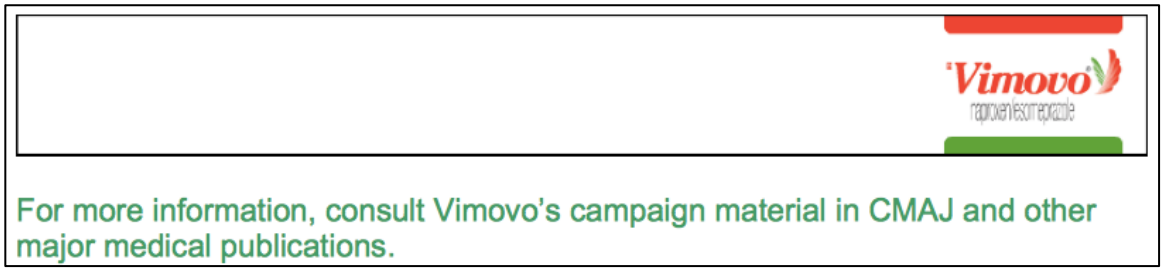

Figure 6. Content of click-through PDF for Vimovo banner ad

Type 4: Name and indication advertisement with link to physician resources

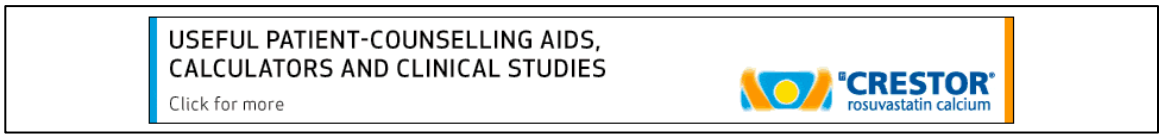

Figure 7. Online journal advertisement for Crestor

Figure 7 shows an advertisement for Crestor. This advertisement clicks through to a site that gives more information on Crestor for healthcare professionals, that is protected through a security question that asks about the starting dose of Crestor. While this question would almost certainly be easier for a physician to answer, the correct value is relatively easy to obtain from a Google search.

Notably, this advertisement also rolls over to a page that shows name, indication and safety information that would not be permitted in an advertisement to consumers (see Figure 8). Yet, there is no restriction on members of the general public viewing this advertisement.

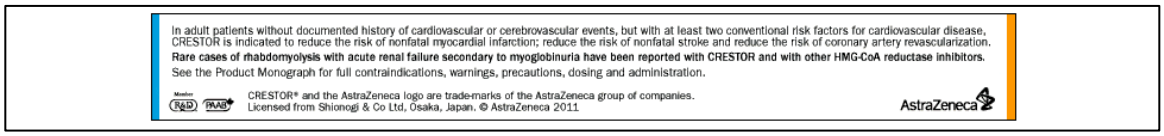

Figure 8. Page Rollover for Crestor advertisement

Type 5: Generic advertisement with link to physician resources

Figure 9. Online journal advertisement for AstraZeneca's ASK service

Figure 9 shows a link that appeared on the Canadian Family Physician website that links to an information site run by AZ for healthcare professionals. The advertisement contains no drug names, and the linked site confirms the individual is a healthcare professional through the use of the provider number.

Summary

While print medical journals can contain product advertisements aimed at healthcare professionals, the move of most major medical publications online means that they are accessible by a broader audience. This is particularly an issue for medical journals that use an "open access" model and can be accessed by any reader. My review found that there are several different types of banner advertisements currently being used in these publicly accessible journals. As an increasing number of medical journals are publishing their content online in an open-access format, PAAB should consider the guidelines under which these journals operate in future revisions of the Code.

Research Question 4: What Internet Social Media activities are Canadian pharmaceutical companies engaged in? What are they planning? What are the major barriers?

The results above suggest that while the Internet is a growing source of information for Canadians, the online prominence of Canadian manufacturers is relatively low. Further, the results from my online searches revealed very little Internet social media activity by Canadian manufacturers. This section of the report outlines the results of a brief survey conducted by PAAB to assess the use of and barriers to Internet social media participation by Canadian pharmaceutical manufacturers.

Methods

In December 2011, PAAB conducted an online survey of pharmaceutical manufacturers investigating their use of social media. The questions for this 7-question survey are shown in Appendix 1. The content focused on the current use of Internet social media sites, the planned future use of such sites, the barriers companies perceive in using social media and what changes they would propose be made to Section 6.5 of the PAAB code. The survey was sent to the individual responsible for public relations at Rx&D member companies and responses were submitted online using the surveymonkey.com system. The online survey was available for responses for 3 weeks after the email invitation was sent.

Results

Responses to the survey were received from 18 companies. In large part, the results confirmed the findings above that the social media presence of most Canadian companies is currently quite limited.

Current and Planned Use of Social Media

Figure 10 shows the reported use of major social media sites by Canadian companies. The figure shows that Facebook is the most commonly used social media site; however, only about 40% of the companies who responded currently have a Facebook page, and only 1 further company is planning to develop a page. For other popular social media sites, the highest rate of use is YouTube, where approximately

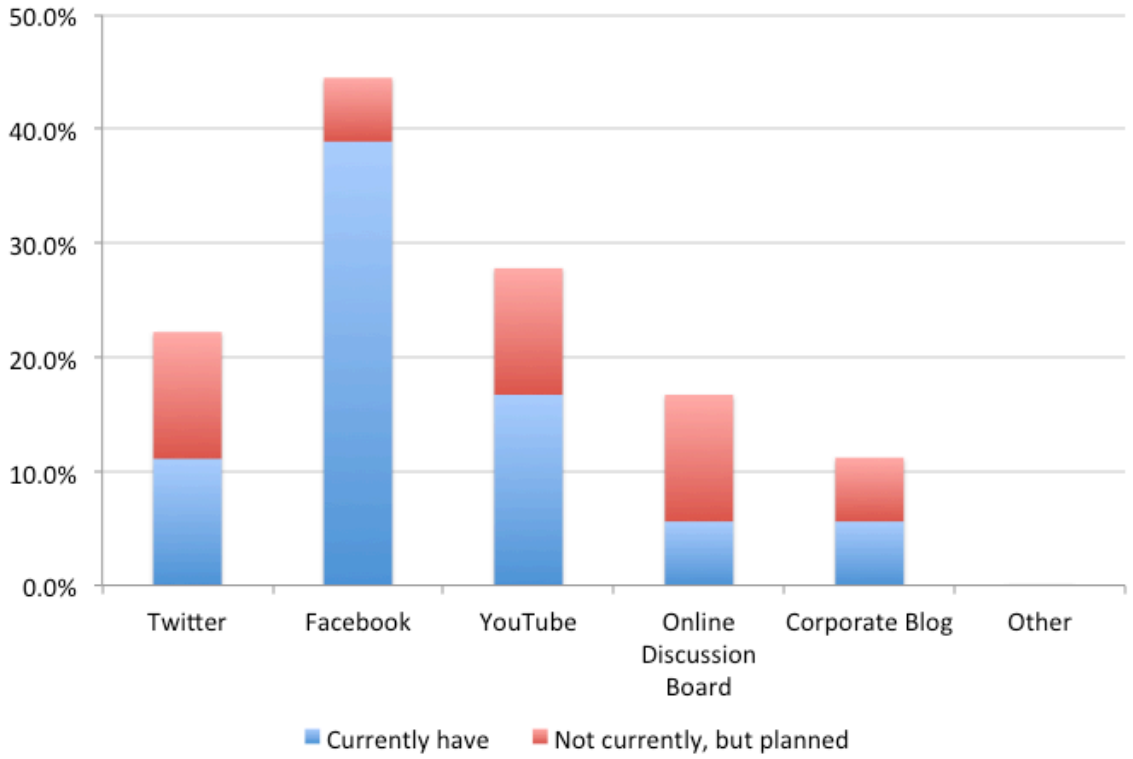

Figure 10. Reported use of different social media avenues by Canadian pharmaceutical companies

30% of companies have or are planning to develop a presence.

The lack of social media use was also apparent when asking about the use of Internet social media by other Canadian manufacturers. Nearly 60% of respondents claimed they were not aware of any Internet social media sites run by Canadian pharmaceutical companies. When asked to identify the best example of social media use by a Canadian company, only two sites were identified: EMD Serono's MS Village and Pfizer Canada's Facebook page.

Barriers to Use of Social Media

The main barriers to using Internet social media that Canadian pharmaceutical firms reported are shown in Table 14 (note that only 17 respondents completed this question). The responses indicate that three potential barriers to participation in social media were deemed the most important: (1) an unclear regulatory framework for social media was reported by 53% of respondents, (2) the current regulatory restrictions and requirements were cited by 29% of respondents, and (3) the time required to monitor and respond to comments was identified by the remaining 18% of respondents. When asked to identify any barrier that was a factor, 82% identified an unclear regulatory framework and 71% identified the current regulatory restrictions.

Potential Barrier	A Factor	Most Important
Unclear regulatory framework for social media	82.4% (14)	52.9% (9)
Current regulatory restrictions and requirements for social media	70.6% (12)	29.4% (5)
Time required to monitor and respond to comments	70.6% (12)	17.6% (3)
Lack of knowledge and expertise in social media development	41.2% (7)	0.0% (0)
Cost of developing a social media presence	35.3% (6)	0.0% (0)
Difficulty measuring the success of campaigns	29.4% (5)	0.0% (0)
Unclear or low expected returns from investment in social media	17.6% (3)	0.0% (0)
Other: Internal approval hurdles	5.9% (1)	0.0% (0)
Other: Potential complex medical legal question in regards to responses on a site related to disclosure	5.9% (1)	0.0% (0)
Other: potential negative impact on products / franchise (lack of control when this information is out in 'cyberspace')	5.9% (1)	0.0% (0)

Table 14. Barriers to the use of Internet social media sites reported by Canadian pharmaceutical companies (n=17)

Beyond regulatory issues, many internal company concerns were identified by respondents, including the time required to respond to comments (71%), lack of knowledge and expertise in social media (41%), difficulty measuring success (35%) and unclear returns from social media investment (18%). Three other potential barriers were also suggested and manually input by respondents, including internal approval hurdles, potentially complex legal questions related to disclosure on the site, and a potential negative impact on products due to lack of control over the Internet.

With respect to the current regulatory environment, some of the responses to the open-ended questions provided insight on the barriers companies perceive, including:

1. Two respondents indicated that it is "nearly impossible" for a company to participate in Internet social media when indication and product name cannot be posted together.
2. One respondent pointed out that it is not possible to limit the audience on Twitter, Facebook and YouTube to healthcare professionals, limiting the use of these avenues for promotion to healthcare professionals.

With specific reference to Section 6.5 of the PAAB Code, respondents made the following specific suggestions for code revision:

1. Two respondents desired guidance from PAAB on how companies can participate in a dialogue online, in particular "correcting errors" and "scientific facts". There was a particular desire for guidance on how companies can do this on forums such as Twitter, which place strict limits on the length of responses.
2. With respect to the preamble to Section 6.5, one response pointed out that not all Internet APS are designed to "aid representatives" and suggested this wording be revised.
3. With respect to Section 6.5.11, there was a request for PAAB to permit electronic submission of sites through a password-protected extranet accessible only by the company and the PAAB reviewer, rather than exclusively through a printed copy.

Research Question 5: What guidance is provided about online activities in other countries?

As part of this review, I reviewed the current guidelines in place regarding Internet advertising and Internet social media activities in both the United Kingdom and Australia. While the United States would also have been a country of interest, the US FDA has not released any guidance on the use of social media to date, aside from guidelines about how companies are permitted to respond to unsolicited requests for off-label information.[16]

United Kingdom

In the UK, the Prescription Medicines Code of Practice Authority indicates that all Internet materials should meet the aspects of their advertising code. In addition, they have produced specific guidance regarding the Internet and social media.[17] Of note, the guidance specifically states that Twitter promotion to healthcare professionals would likely not be permissible, as it would be impossible to limit the audience to not include the general public (to whom advertising is not permitted in the country). Moreover, the guidance suggests that promoting a specific study via Twitter would likely be considered promotion.

In addition, the Association of the British Pharmaceutical Industry (ABPI) Code of Practice contains certain provisions that are relevant to the Internet and social media content.[18] For example, section 4.6 contains the following two provisions:

1. "In the case of promotional material included on the Internet, there must be a clear, prominent statement as to where the prescribing information can be found."
2. "In the case of an advertisement included in an independently produced electronic journal on the Internet, there must be a clear and prominent statement in the form of a direct link between the first page of the advertisement and the prescribing information."

Other sections of the code permit so-called "abbreviated advertisements" in professional publications that are exempt from providing the full prescribing information (section 5). However, these advertisements are specifically not permitted on the Internet, including in online journals (section 5.2). Finally, section 24 on the Internet stipulates that information on the Internet must conform to other areas of the code. Further, the code suggests that manufacturers include reference materials for their medicines in a non-promotional manner.

The ABPI has also produced relevant guidance entitled "Guidance notes on the management of adverse events and product complaints from pharmaceutical company sponsored websites".[18] With reference to adverse event reporting (AER), the guidance states that companies must screen websites under their control regularly, and report AERs within 15 days. For a report to able to be validated, the site should allow collection of (1) an identifiable patient, (2) a suspect drug, (3) an adverse event, and (4) an identifiable reporter. Screen names and email addresses would be considered acceptable identification if they allow contact to be made with the individual reporting the event.

This document also provides more general guidance on the use of Internet sites and social media by pharmaceutical manufacturers. Notably, the document recommends that pages under the control of a pharmaceutical firm conform to the following criteria, some of which might be useful to emulate in Canada:

1. Company involvement in running the site must be transparent. It is worth noting that this is not currently the case in Canada for all sites. For example,

the social media discussion board site msvillagecanada.ca appears to be sponsored by EMD Serono, but this is only apparent on the "Contact Us" link, which is at the bottom of the page in small typeface.
2. They company disclose how long they intend to sponsor the site.
3. The company provides information on how they screen content and provide notice that it may not publish content that contravenes regulations. To this end, the guidance also suggests that user postings be moderated before publication to the site.
4. They recommend that a company provide a means to report AERs on the site. No explicit guidelines are given for monitoring requirements, but daily monitoring is recommended.

Australia

In August 2011, Medicines Australia, the self-regulatory body of Australian pharmaceutical manufacturers, released version 16.2 of their Code of Conduct, which contains updated sections on both activities on the Internet and on social media in particular. Notably, the code specifically states that all activities on the Internet should be considered a relationship with the general public. The code encourages companies to make the Consumer Medication Information, which must be included in its entirety, on their websites. This is roughly similar to what I found is currently included on the Canadian manufacturers' sites I reviewed, where the product monograph was a universal feature. Further, the Australian Code allows for the development of password-protected sites for patient information, and specifically suggests the use of the AUST R number as a password (similar to a DIN).

The Australian Code allows links to the global site for their company, as long as it is accompanied with a disclaimer that the content may not comply with Australian regulations. This is in contrast to the PAAB code, which specifically disallows links where the content may contravene Canadian regulations (Section 6.5.5).

With respect to social media, the Code provides some very general considerations that manufacturers should undertake prior to launching a site. These guidelines are more general than the UK equivalents, and include:

1. Determining whether and how often discussion boards need to be monitored;
2. Establish rules about what type of posting is appropriate (for example, promotion of a product would not be permitted), and describe the process for excluding such content from the site;
3. Include a proviso stating that the site could be shut down at any time.

Discussion: What updates should be incorporated into the PAAB Code to meet the demands of new online advertising activities?

The above findings suggest that while most Canadians are receiving their prescription drug information online from non-Canadian sources, many Canadian

manufacturers have an online presence. While the use of social media by Canadian pharmaceutical manufacturers is in its infancy, it is important that regulation and guidance be clear about the duties and expectations of manufacturers. Such guidance would avoid a situation where regulatory authorities are required to issue reprimands, as has happened in the United States with Facebook activities by manufacturers.[19]

Currently, the PAAB Code addresses certain aspects of Internet advertising in Section 6.5, entitled *Internet, Audio, visual, Audio/visual (Av), Electronic APS*. Below, I recommend some changes based on my findings of what is currently occurring in the online space in Canada, along with the areas addressed by other countries.

Recommendations

Overall Recommendations

18. Given the rapid growth of the use of the Internet by the public, I would recommend splitting the Advertising/Promotion Systems (APS) currently included in Section 6.5 into three separate sections: (1) Internet Web Site APS, (2) Social media site APS, and (3) Audio, visual, Audio/visual (Av) and Electronic APS. This would allow the creation of code items that address the unique features of each type of advertising. Below, further recommendations will be divided between proposed Section 1 and 2.

19. Currently, Section 6.5 only discusses activities where the "likely audience is Canadian health professionals". Given the range of websites detailed above and their different target audiences, I recommend expanding the definition to include sites directed at consumers and patients. This is important, as the different audiences will require different guidance (such as different access restrictions) and/or pre-clearance.

20. As evidenced by the results from the survey of manufacturers, there remains a significant degree of confusion about the regulatory requirements for both general Internet and more specifically Internet social media activities. I wonder if decision aids would facilitate increased knowledge about Canadian regulations. These might take the form of flow charts with key questions about site content (e.g. "Who is the target audience for the information?" and "Will user comments be permitted on the site?"). Along with potentially reducing regulatory violations, this might also increase the knowledge about areas that are currently not well described in regulations.

21. The wording of Section 6.5 should be modified to include all Internet APS, not just those "designed to aid representatives".

22. PAAB should consider allowing electronic submission of Internet APS through private, password-protected access for reviewers.

Internet Web Site APS

Sites directed at consumers

23. The Code should specifically state that web sites directed at the general public should contain the entire product monograph (or Section 3 of the monograph in it's entirety). This would remedy a problem we identified with a manufacturer's site in the preliminary work for this project, where the web page only presented sub-sections of Section 3.

24. Medical journals that contain advertising and are openly accessible should be considered as advertising to the general public. Thus, they should only be advertising on name, brand and price. I recommend the Code should be modified to indicate this change, and advertisements in publicly accessible medical journal websites should link to a pdf that recommends consulting the print version of medical journals for further information (Type 3 in the typology I discussed above on page 26).

25. My review of Canadian pharmaceutical firm websites revealed some significant concerns about news releases (see section starting on page 24). Thus, I recommend that the revised version of the PAAB Code contain specific guidance around news releases that are contained on publicly accessible web pages sponsored by pharmaceutical companies. Current Health Canada guidance suggests that news releases should be "directed to shareholders", so I would recommend at a minimum that online copies of releases should indicate they are "For the Information of shareholders only" at the top of each release. Further, given the seemingly promotional nature of some of the releases, PAAB might consider either providing or requiring pre-clearance services for the content of news releases that will be posted online and accessible to the general public to ensure they are not considered advertising or are compliant with the advertising regulations.

26. Linking to other sites is an important consideration when determining whether a web page is advertising. However, the current wording in the section on links to other sites (6.5.5) indicating "close proximity" is vague and should be more clearly defined in terms of the number of "clicks" that are covered.

27. Any brand name reminder sites and patient discussion boards should be required to have details regarding the sponsoring company on every page (see above discussion of Champix.com site, and of msvillagecanada.com).

Sites directed at patients

28. Given the ease with which DINs can be obtained (as detailed above on page 22), I would recommend that section 6.5.6 be modified to ensure federal regulations regarding audience are being enforced. This might take the form

of a leaflet provided by a prescriber, a package insert containing a password, or a similar package feature that would not be easily obtainable online.

Sites directed at healthcare professionals

29. Similar to the above recommendation about updating the password protection on sites aimed at patients, I recommend that sites aimed at providers have a standard and consistent entry system. I would suggest that this system require healthcare providers to register and their provider number be entered. This would avoid members of the general public gaining access through questions that can be easily guessed or obtained (such as the question on Crestor's site about starting dose discussed above on page 26).

Social Media

30. As stipulated in PAAB guidance on the topic, sponsor companies are responsible for the comments and user postings on their social media sites.[20] I recommend that the next version of the PAAB code should include specific guidance about this requirement and about the required timelines for site monitoring. This could take one of two forms: either a requirement that companies pre-vet material before it is published on the site, or a short timeframe in which comments must be reviewed for content (such as one business day). The first method, pre-vetting, would provide the highest level of compliance with regulations.

31. As social media sites that allow comments and postings by users might result in reportable adverse events, I recommend that the next revision of the PAAB Code contain explicit timelines for reporting. In the UK, screening for adverse events is to be completed on a daily basis, and reports must be submitted within 15 days. A proposal for reviewing the site and submitting reports should be included with each new social media site submissions.

32. Social media sites sponsored by pharmaceutical manufacturers should provide a system for submitting adverse event data (as in the UK).

33. Company sponsorship of a social media site should be disclosed on every page of the site. In addition, companies should disclose how long they intend to sponsor the site (as in the UK).

34. Advertising to healthcare professionals and patients using either Twitter or Facebook should not be permitted, as it is not possible to restrict access to these groups.

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Appendix 1. Survey Content

Survey Preamble

The PAAB is looking for possible revisions to Section 6.5 of the PAAB Code of Advertising Acceptance. As part of the overall code review process, the PAAB is conducting research to discover what Canadian prescription product pharmaceutical companies have been doing online. We are complementing our online research with a survey of manufacturers. This information is very important to the PAAB.

We would appreciate that this survey be completed once per company and that you forward the survey to personnel who are most familiar with online activities for completion and return.

Thank you for taking the time to respond to our survey on social media use by Canadian pharmaceutical manufacturers. This survey consists of 7 questions. All responses will remain anonymous and only be reported in aggregate. You have PAAB confidentiality. Responding to each question is optional.

Page 1

1. Do you currently have, or plan to develop, the following types of Internet social media sites for promotional purposes? Please only include activities undertaken within Canada.

	Yes	Not currently, but planned	Not planned
Twitter	○	○	○
Facebook	○	○	○
YouTube	○	○	○
Online Discussion Boards	○	○	○
Corporate Blog	○	○	○

Other types of social media site not listed above

Page 2

2. Are you aware of any social media sites sponsored by Canadian pharmaceutical manufacturers?

- ◯ Yes
- ◯ No

3. If you answered yes to the above question, when you think of social media use by Canadian pharmaceutical manufacturers, what site stands out to you as the best example? Feel free to indicate particular websites, twitter feeds, facebook pages or other social media sites.

Site name _____

Site address _____

Page 3

4. In our study of the Internet activities of Canadian manufacturers, we found a limited amount of online promotional activity. What barriers do you think are preventing Canadian firms from engaging in Internet social media (such as Facebook, Twitter and YouTube)? (Multiple selections permitted).

- ☐ Cost of developing a social media presence
- ☐ Time required to monitor and respond to comments
- ☐ Lack of knowledge and expertise in social media development
- ☐ Unclear or low expected returns from investment in social media
- ☐ Current regulatory restrictions and requirements for social media
- ☐ Unclear regulatory framework for social media
- ☐ Difficulty measuring the success of campaigns

Other (please specify)

_____

5. Of the barriers you identified above, which do you believe is the single most important?

- ◯ Cost of developing a social media presence
- ◯ Time required to monitor and respond to comments
- ◯ Lack of knowledge and expertise in social media development
- ◯ Unclear or low expected returns from investment in social media
- ◯ Current regulatory restrictions and requirements for social media
- ◯ Unclear regulatory framework for social media
- ◯ Difficulty measuring the success of campaigns
- ◯ Other

Page 4

6. Do you have any changes you would suggest be made to Section 6.5 of the PAAB Code, section 6.5, which deals with Internet activities?

(Note: the current version of the PAAB code can be viewed at http://tiny.cc/al196)

7. Do you have any other thoughts on the use of online social media by Canadian pharmaceutical manufacturers?