Regulating Direct-to-Consumer Drug Information: A Case Study of Eli Lilly's Canadian *40over40* Erectile Dysfunction Campaign

Réglementation de l'information destinée directement aux consommateurs : étude de cas de la campagne *40desplusde40* d'Eli Lilly sur le dysfonctionnement érectile

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Abstract

Like most jurisdictions, Canada prohibits direct-to-consumer advertising (DTCA) of prescribed drugs. However, direct-to-consumer information (DTCI) is permitted, allowing companies to inform the public about medical conditions. An analysis of Eli Lilly's *40over40* promotion campaign for erectile dysfunction (ED), which included a quiz on ED, shows that DTCI, like DTCA, can be an effective means of drug familiarization. The pharmaceutical industry is "playing by the rules" currently in effect in Canada. Regulators should thus seriously consider whether existing rules permitting DTCI actually meet stated objectives of protecting the public from marketing campaigns (i.e., DTCA) that may deliver misleading information.

Résumé

Comme dans la plupart des pays, le Canada interdit la publicité directe auprès des consommateurs (PDAC) pour les médicaments sur ordonnance. Toutefois, on y autorise l'information destinée directement aux consommateurs (IDDC), permettant ainsi aux compagnies d'informer la population sur certains états de santé. Une analyse de la campagne de promotion *40desplusde40* d'Eli Lilly sur le dysfonctionnement érectile (DE) – laquelle comprenait un questionnaire sur le DE – démontre que l'IDDC, comme la PDAC, peut constituer un moyen efficace de familiarisation a un médicament. L'industrie pharmaceutique « se plie aux règles du jeu » actuellement en vigueur au Canada. Mais les organismes de réglementation devraient sérieusement s'assurer que les règles qui permettent l'IDDC atteignent réellement les objectifs en place visant à protéger la population des campagnes de marketing (à savoir la PDAC), lesquelles peuvent donner une information trompeuse.

For decades, access to and use of prescription drugs has been controlled by health professionals, and almost exclusively by physicians. It is widely recognized that, due to their potency and potential harms, many drugs should be available only by prescription, i.e., their use authorized by and made available to patients under the supervision of a physician (Donohue 2006). Most developed countries have implemented legislation to control how drugs are developed and marketed to the public (Carter 1999; Rosenthal et al. 2002), because prescription drugs should not be marketed like other commodities.

In the Canadian context, as in most jurisdictions (the US and New Zealand being notable exceptions), direct-to-consumer advertising (DTCA) of prescription drugs is prohibited because of important concerns about patients' misunderstanding of a drug's benefits/risks, thereby contributing to potential misuse, specifically increased demand by patients (Findlay 2001) and pressure on physicians (Lurie 2009) to prescribe marketed drugs (usually brand-name drugs), and thus increasing pressure on the budgets of health insurers (public or private) (Mintzes et al. 2003). The Canadian Food and Drugs Act prohibits the use of promotional activities and advertising that includes "false, misleading or deceptive" information, and it also

restricts drug promoters from "mak[ing] any representation other than with respect to the brand name, proper name, common name, price and quantity of the drug" (Food and Drugs Act 2013). Unfortunately, as Lexchin and Mintzes (2014) demonstrate, there are important weaknesses in the enforcement of Canadian DTCA regulation, most notably with regard to the promotion of "off-label" uses, financial inducements to use a product, fear-generating advertisements and advertising of products with serious safety concerns.

However, Canadian regulation has undergone a series of reforms that have allowed the pharmaceutical industry to employ other strategies to promote their products (Gardner et al. 2003; Lexchin 2013). In the wake of these reforms, Health Canada mandated two independent organizations – Advertising Standards Canada (ASC) and the Pharmaceutical Advertising Advisory Board (PAAB) – to oversee the application of Food and Drugs Act provisions regarding drug promotion. Termed "direct-to-consumer information" (DTCI) by ASC, informational campaigns – which may include brochures and websites, help-seeking announcements (e.g., TV spots) and social media – are permitted in Canada when the putative aim is to raise awareness about a particular medical condition and available treatments, but this information cannot mention a specific product or manufacturer (ASC 2011). This distinction between non-permitted "advertisement" and permissible "information" is based on provisions in the Health Canada policy, The Distinction Between Advertising and Other Activities, which "recognizes the importance to the pharmaceutical industry and to the general public of being able to disseminate and access non-promotional information regarding drugs for human use" (Health Canada 2005). It should be noted that the mandate of ASC is limited to materials submitted on a voluntary basis by pharmaceutical companies, and it can only provide non-binding recommendations. Further, even if ASC issues guidelines, it does not have the authority to adjudicate complaints, which remains the responsibility of Health Canada.

When assessing the impact of particular marketing strategies on peoples' perspectives and knowledge about available treatment options, attention to purpose and business context (e.g., competitor drugs or treatments on the market) is also important when regulators try to distinguish between advertising and the more ambiguous concept of promotion. Both advertising and promotion are ways to increase customer attention towards and sales of a product (Canadian Marketing Association 2013), and these may be used to present or reinforce a product's image (e.g., as the gold-standard treatment) and/or a corporate brand (Leiss et al. 2013). However, there is a fine line between the two concepts. Rather than being treated as advertising, i.e., "Any paid form of non-personal communication about an organization, product, service, or idea by an identified sponsor" (Alexander 1965: 9), we suggest that DTCI – with its multifaceted design – lies more in the realm of promotion, i.e., "The coordination of all seller-initiated efforts to set up channels of information and persuasion to sell goods and services or to promote an idea" (Belch and Belch 2008).

Considering that, in terms of regulation, the ASC is responsible for framing Health Canada provisions on drug-related communication activities, it is pertinent to use their distinction between DTCI and DTCA to better understand how DTCI works in practice

under current Canadian regulation, and then to evaluate whether this distinction is valid (i.e., whether DTCI is in fact free from the problems associated with DTCA). To facilitate this analysis, we examine Eli Lilly's *40over40* DTCI campaign about the problem of erectile dysfunction (ED). We conclude that this campaign – and DTCI in general – can be a very effective and subtle means of building public familiarization with a particular product (e.g., Cialis), raising most if not all of the same concerns that led governments to restrict DTCA.

DTCI in Action: Eli Lilly's *40over40* Campaign

In 2010, Eli Lilly launched *40over40*, a Canadian DTCI campaign for ED to promote its drug Cialis. The campaign complied with Canadian drug marketing legislation and was certified by the ASC. A *help-seeking* television advertisement presented the medical condition and the burdens of living with ED and referred viewers to the *40over40.ca* website for more information about treatment options. Among an array of information about ED and possible treatments, one of the main features of the website was a quiz that men could take to evaluate if they were among the 40% of Canadian men over 40 years old supposedly with ED (i.e., a good marketing claim that is not adequately referenced on the *40over40* website).

The quiz is a shorter version of the *International Index of Erectile Function (IIEF) Questionnaire*, which was "designed to provide sensitive and specific outcome assessments in clinical trials of ED [with the goal to] develop a self-administered questionnaire that would be suitable for use by clinicians and researchers" (Rosen et al. 1997: 823). The *40over40* campaign used a modified version of the IIEF, a self-assessment quiz for patients (Cappelleri and Rosen 2005). After five general and non-contextualized questions (each scored out of five), if a man's score is lower than 22 out of 25 points, he is identified as being in need of treatment for ED. Interestingly, if he answers "No sexual activity" to the second question "When you had erections with sexual stimulation, how often were your erections hard enough for penetration?" or selects "Did not attempt intercourse" to any of the three next questions, he loses all the points related to that question, thereby placing him in a category considered as abnormal and thus requiring treatment. No matter the context of or the reasons for a lack of sexual function or activity, the website and quiz reports that this is likely due to a problem of ED that can and should be treated. Further, whether or not the score reaches the "abnormal" threshold, the same general statement is presented to the viewer:

> If your score is 21 or lower, you may want to speak with your doctor. Only your doctor can confirm if you have ED, so talk to him or her about these results. If you do have ED, remember that you're not alone. There's no need to worry or feel embarrassed. ED is a very common condition affecting about 40% of men over 40 years of age. Luckily, there are many available treatments to consider, and up to 95% of ED cases can be treated. Learn about your options and then make an appointment to discuss them with your doctor (Eli Lilly Canada Inc. 2014).

The quiz's form and presentation give the impression that it is a standard clinical evaluation, but without any empirical justification to support its claims or the need for respondents to seek medical advice. Overall, because of logical shortcuts (e.g., that no sexual activity necessarily implies ED) and lack of references, the scientific validity and trustworthiness of the tool is questionable. But the intent is clear: to convince men that, no matter their situation (i.e., their score on the quiz), they should still talk to their physician about ED and seek treatment.

The Business Context of Drug Familiarization

The business context of a drug information campaign can be an important factor in familiarizing the public with a drug, an element that current legislation is unable to take into account. To continue with the *40over40* example, Cialis has dominated Canadian public media in recent years, with a noted increase in its media presence (e.g., TV, websites or social media) compared with a significant decrease for Viagra. In part, this can be explained by the fact that:

1. Viagra is a slightly older drug and so is marketed less than more recently commercialized drugs (Wienke 2005).
2. There is a general absence of advertising from the other competitors, Bayer and GlaxoSmithKline, mostly because of recent market saturation and lack of features to differentiate their drugs from the market leaders, Cialis and Viagra (Dawar 2013).
3. Pfizer (makers of Viagra) lost its Canadian patent two years before its legal expiration in 2014, following a Supreme Court of Canada decision that voided the patent because of a lack of disclosure in the original patent application of the actual compound treating ED (Teva Canada Ltd. v. Pfizer Canada Inc. 2012). This likely dampened Pfizer's interest in marketing Viagra.

As a result, Cialis is the only product being actively promoted for ED in Canada, which may subtly orient people to think of this drug as the gold-standard treatment, rather than considering alternative drugs or non-medical interventions. So even if the stated (and government-approved) purpose of the *40over40* campaign is help-seeking, questions should be raised by the ASC as to whether this campaign is not *too effective* at achieving this goal, i.e., that it may be very effective at familiarizing the population with a particular and one-sided view of a condition, in terms of severity, incidence and treatment options. For example, there is evidence that drugs are not the sole effective treatment of ED, and that improvement in erectile function is possible through a risk reduction approach (Martin et al. 2014) and behaviour modification, such as choosing more healthy lifestyles, addressing the co-morbidities of aging, stress reduction or seeking counselling or psychotherapy. But this evidence is not presented in the information campaign, and so, viewers are left with a limited array of possible treatment options, of which drugs are favoured (Bélisle Pipon and Williams-Jones 2015).

The Impact of Familiarization

Even with the limited amount of information permitted in DTCI campaigns in Canada, they can, thus, still be a very effective and subtle means of familiarizing the public with a prescription drug, a disease or a company. Further, the public may be unable to evaluate the veracity of advertised claims, especially when the apparent purpose of the marketing campaign is to inform. Familiarization is particularly effective in an era where patients are increasingly seen – and may see themselves – as consumers of health services (Featherstone 2010), and where pharmaceutical drugs are seen as commodities (Cohen et al. 2001). Because they are familiarized with a specific drug, consumers of medical information may develop misconceptions with regards to the nature of their medical condition (e.g., incidence, severity) and the benefits and (lack of) risks of drugs (or other products) promoted to treat the condition (Bélisle Pipon and Williams-Jones 2015). Such misconceptions may be especially problematic in the case of ED, with drugs such as Cialis and Viagra having a highly symbolic role in the collective imagination.

Interestingly, Canada is not the only jurisdiction that struggles with regulating DTCI-like activities; for instance, the Netherlands has similar dispositions allowing disease awareness campaigns that are framed by a self-regulated agency. A study from Leonardo Alves et al. (2014) demonstrated that there is low compliance with self-regulation guidelines in the Netherlands. Even if their study was focused on the print media, the authors raised questions about the growing interest for online drug information and the importance of evaluating "the content and quality of disease awareness websites" to determine the effect on consumer behaviour (Leonardo Alves et al. 2014: 8).

In the same vein, while assessing a low-testosterone, unbranded online campaign in the US, (Schwartz and Woloshin 2013) identified three familiarization strategies that can also be found in the *40over40* campaign: lowering the bar for diagnosis (e.g., by using an exaggerated abnormal threshold in the ED self-assessed quiz), overemphasis of the risks to push patients to consult their doctor (e.g., by exaggerating the potential consequences of ED) and orienting interpretations of the evidence about drug benefits and harms (e.g., by emphasizing drug functioning rather than other potential options to address the causes of the disorder, such as stress reduction). These strategies have a significant familiarizing effect, because they are integral to "well-coordinated campaigns [that] are more subtle than drug-specific campaigns, and they blur the line between public health or professional education and marketing" (Schwartz and Woloshin 2013: 1461).

Conclusion

It is important to note that pharmaceutical companies engaged in DTCI in Canada, such as Eli Lilly in its *40over40* marketing campaign for ED, are playing by the rules set by Health Canada. Thus, if the goal of health regulators is to mitigate the potential undue influence created by drug advertisement (i.e., current restrictions on DTCA) (Bélisle Pipon 2013), then regulators should acknowledge that DTCI raises similar ethical problems as DTCA. They

should protect the public from activities that have a familiarizing component that undermines the ability of people (i.e., patients and health professionals) to make free and informed decisions about how to best manage and find treatments for particular medical conditions. More specifically, regulators should consider treating DTCI as an indirect but powerful form of advertising that can familiarize people with certain drugs, and so apply similar restrictions to DTCI as for DTCA. Rather than DTCI being treated as a self-regulated activity, and thus being subject to only voluntary evaluation by ASC, information campaigns should be assessed under the current and more strict (if still limited) regulation for DTCA. In addition, the business context should be considered when a campaign is assessed, so that a non-promotional campaign does not end up promoting one drug as the gold standard. In so doing, regulators could eliminate important ambiguities surrounding the notion of DTCI as being relatively neutral "information provision" and close important loopholes in current regulations.

Recognizing that DTCI is most often drug promotion – in the sense of the World Health Organization (1988: 5) definition, where "'promotion' refers to all informational and persuasive activities by manufacturers and distributors, the effect of which is to induce the prescription, supply, purchase and/or use of medicinal drugs" – and thus an indirect form of advertising means that it should, more generally, be regulated alongside DTCA activities. This would, we suggest, help to make the "rules of the game" for drug marketing clearer and more robust, and also better protect the public and help professionals from initiatives designed to subtly influence their behaviour.

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