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Selection, clearance and registration

Health Canada

In Canada, prescription drugs can be sold only once they have successfully completed the drug review process and a notice of compliance (NOC) and drug identification number (DIN) have been issued. The Therapeutic Products Directorate of Health Canada will assess the safety, efficacy and quality of a drug; if it concludes that the benefits outweigh the risks, the drug will be issued an NOC and DIN. These designations indicate that the drug has been officially approved for sale in Canada.

Under the Canadian Food and Drug Regulations (Sections C.08.002 and C.01.014.1), the name of a proposed drug must also be provided in the drug submission. Health Canada will review all proposed drug names as part of its drug review process; if a potentially confusing

name (ie, one that looks and/or sounds similar to another drug) is identified during the review, the manufacturer will be required to change the name of the proposed product. This is to prevent medical errors resulting from the dispensation, use and/or sale of one product instead of another when two product names look and/or sound alike.

Trademark registration

The drug approval process in Canada is separate and distinct from trademark registration. Registration of a trademark for a pharmaceutical product name does not ensure that the name will be accepted by Health Canada. Similarly, even if a product name is approved by Health Canada, it may not be registrable as a trademark.

In the case of trademark registration, the Trademarks Office considers whether the use of similar trademarks will create a likelihood of confusion as to the source of origin of the products. If two drug products have similar therapeutic indications and the drug names are also similar, then trademark registration may be refused on the basis that

consumers are likely to be confused into thinking that the drugs emanate from the same source of manufacture.

By contrast, Health Canada looks at the visual and phonetic similarities between the drug names to determine whether they can co-exist in the marketplace from a safety perspective, bearing in mind the likelihood of medication errors and the potential for harm. For example, the consequences of the patient missing the pharmacological action of the intended drug and the pharmacological actions and toxicities of the unintended drug will often be considered.

In addition to issues of confusion, trademarks are examined for descriptiveness and will be rejected if they are considered to be the same as, or too similar to, an international non-proprietary drug name. This issue is often raised in the course of opposition proceedings initiated by a third party alleging that the mark applied for is descriptive of the product. For example, in *Johnson & Johnson v Taro Pharmaceuticals Inc* [(1998), 87 CPR (3d) 338 (TMOB)] the proposed mark MICROZOLE

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was held to be clearly descriptive of pharmaceutical preparations containing miconazole nitrate.

Non-traditional trademarks

In Canada, a trademark consisting of a colour (or colours) applied to a particular shape and size of a pharmaceutical tablet is inherently registrable. Indeed, in 1950 the Canadian Trademarks Office issued a registration for a blue tablet trademark described as “a blue tablet of spherical triangular shape or shaped somewhat like a heart” (Registration UCA38066). The application issued to registration unopposed. Since then, however, virtually all trademark applications for colour tablet or capsule marks have been opposed by third parties, primarily on the ground of non-distinctiveness (ie, that the mark applied for cannot serve to distinguish the product from other products on the market).

While Canadian courts have consistently held that colour applied to a pharmaceutical tablet or capsule is inherently registrable, there is a high evidential burden on the applicant to establish distinctiveness at all consumer levels (including the patient, pharmacist and prescribing physician), and with respect to other pharmaceutical preparations available on the market, regardless of the specific medication and/or end uses of the drug. As a result, non-distinctiveness continues to be a significant hurdle in the trademark registration process for colour tablets or capsules.

Canadian trademark law will also protect the shape of a tablet or capsule. However, protection can be obtained by way of a distinguishing guise registration, rather than ordinary trademark protection, since such marks are now generally considered to be the “shaping of the wares or their containers”.

Parallel imports and repackaging

Pharmaceutical preparations that are to be sold in Canada must receive prior Health Canada approval to market, without which sales of the product will be prohibited. Moreover, all such preparations must comply with Canadian labelling requirements as set out in the Food and Drug Regulations, including Section C.01.005, which requires that the inner and outer label of a drug display the DIN assigned for that product. Accordingly, the parallel importation of pharmaceutical preparations into Canada that have not received Health Canada approval and that do not bear the requisite DIN may be illegal, even though the drug has been approved for sale in another country.

Given the comparatively low cost of pharmaceuticals in Canada as compared to many other countries (due in large part to substantial regulations and price caps on pharmaceuticals), Canada has the potential to expand exports of less expensive drugs into the United States and other countries. However, the Canadian Pharmacists Association, the Canadian Medical Association and Health Canada have all produced position papers against the exportation of cheaper drugs from Canada into other countries, especially where the patient has no relationship with a Canadian pharmacist and doctor or where there are drug shortages in Canada. Such dialogue has resulted in several initiatives that have reduced the flow of lower-priced pharmaceuticals out of Canada over recent years.

Anti-counterfeiting and enforcement

Counterfeit pharmaceuticals include both brand-name and generic medicines that are deliberately and fraudulently mislabelled with respect to their identity and/or source. They can be produced with incorrect or

poor-quality medicinal ingredients or insufficient quantities, or can contain toxic or poisonous chemicals.

The magnitude of counterfeit pharmaceuticals in Canada remains relatively small in comparison to other industrialised countries, but nevertheless the problem exists. However, the procedures and remedies available to prevent the importation of counterfeit goods at Canadian borders are inadequate.

The applicable legislation dealing with border enforcement of counterfeit goods in Canada is the Customs Act, IP statutes including the Trademarks Act and Copyright Act, and the Criminal Code.

The Customs Act permits the Canadian Border Service Agency to detain goods that are “prohibited, controlled or regulated” by an act of Parliament. However, there is no act of Parliament (legislation) that specifically identifies counterfeit or pirated goods as being prohibited, controlled or regulated, and hence it is not illegal under the Customs Act to import counterfeit goods.

Moreover, Canada does not have a trademark recordal regime at Customs or any regime for the recordal of other IP rights. As such, customs officials will not act independently to search and seize goods that violate a trademark owner’s rights.

Counterfeit goods can be detained at the Canadian border only in one of three ways:

- a civil action based on a violation of trademark rights under the Trademarks Act;
- a seizure request directly to Customs based on a violation of copyright under the Copyright Act; or
- a violation of criminal law under the Criminal Code.

None of these avenues, however, provides adequate remedies.

The Trademarks Act enables the owner of a registered trademark to apply for an interim court order enabling Customs to seize goods which, if distributed in Canada, would violate the Trademarks Act. However, this remedy is impractical and expensive. A civil action under the Trademarks Act requires knowledge of the impending importation or release into trade of the counterfeit products, which often is not available. Moreover, there are no penal provisions, making an order obtained under this legislation relatively toothless. In addition, Customs will not enforce the order without all the requisite information, and the information needed to support enforcement is very onerous. The combination of a lack of enforcement by customs officials, limited border remedies available under the Trademarks Act and the significant cost of obtaining the order has resulted in very few detention orders under the Trademarks Act being sought and issued.

The Copyright Act contains provisions analogous to those found in the Trademarks Act. However, under Canadian copyright legislation, rights holders can make a seizure request directly to Customs without resort to the courts or the police. Hence, a court order is not required before customs officials will act. In addition, there is no requirement that the copyright be registered, as is the case with an order obtained under the Trademarks Act. Nevertheless, Customs still requires very detailed information to act, making seizure requests under the Copyright Act of limited practical value.

The Criminal Code deals with penalties for forgery or criminal passing off of a trademark (fraud), and for copyright infringement or piracy. The Royal Canadian Mounted Police Force (RCMP) may act on information provided by a trademark holder about incoming shipments of goods which can result in a seizure through Customs. In practice, however, they will do this only in respect of registered trademarks and require much the same information as that required in the case of an order issued under the Trademarks Act – much of which is very difficult, if not impossible, to obtain. Moreover, it is necessary to show criminal intent for proceedings under the Criminal Code.

In 2005 the RCMP investigated a Canadian pharmacist for purchasing and subsequently dispensing counterfeit Norvasc, a heart medication. The product was found to contain talc and several patients died after ingesting the medication. However, the pharmacist was ultimately acquitted, as there was insufficient evidence

to prove criminal intent.

There is also very little deterrent value in the Criminal Code provisions. Financial penalties for forgery or passing off of a trademark include fines of up to C\$10,000 and/or imprisonment for up to two years – often regarded simply as the cost of doing business.

Advertising

Section C.01.044 of the Food and Drug Regulations restricts consumer-related advertising for prescription drugs to the mention of the name, price or quantity. Under this regulatory framework, Health Canada has permitted two types of prescription drug message directed to consumers: 'reminder ads' and 'help-seeking messages'.

Reminder ads, where only the name of a prescription drug is mentioned but not the disease, are interpreted as not going beyond the name, price and quantity restrictions of Section C.01.044. Help-seeking messages, where a disease state is discussed but there is no reference to a specific prescription drug product, are considered 'information' and not 'advertising', provided that they meet the criteria outlined in Health Canada's policy entitled "The Distinction Between Advertising and Other Activities".

Depictions of easily recognisable product packages (eg, blister packs, inhalers) that lead to the identification of the therapeutic indication of a prescription drug in reminder ads are considered to exceed the consumer advertising limitations described in Section C.01.044 of the Food and Drug Regulations and are therefore not permitted in Canada.

Advertising pre-clearance agencies review and pre-clear advertising material in order to help industry to ensure compliance with the regulatory provisions of the Food and Drugs Act and Regulations, the Natural Health Products Regulations and the various Health Canada guidance documents and codes of advertising. The agencies also offer independent mechanisms to resolve complaints on advertising for authorised health products.

Canada's research-based pharmaceutical companies also comply with a code of ethics as a requirement of their membership in their trade association, Rx&D. This code includes advertising guidelines. Violations of the code can result in fines of C\$10,000 for a first offence during a calendar year and up to C\$50,000 for each offence over the third offence in a calendar year. Recidivism or deliberate breach of the code may result in the expulsion of a member company from the trade association.

Generic substitution

Both the federal and provincial governments regulate the pharmaceutical industry in Canada. The federal government has jurisdiction over IP rights of manufacturers and the initial approval and labelling of prescription drugs. The provincial governments have jurisdiction over, and are responsible for, the funding of all healthcare services. Each provincial drug plan sets specific price and other cost-containment guidelines (eg, drug product substitution laws) with respect to the pharmaceutical coverage provided.

Drug substitution regulations have been in place in most provinces for many years. These regulations have typically focused on promoting the substitution of lower-priced generic drugs for brand-name drugs, through the implementation of product and price selection rules. Product selection involves switching from a branded to a generic drug, whereas price selection involves choosing the least costly generic available.

Online issues

Canada does not prohibit the online sale of prescription drugs; however, ordering prescription pharmaceuticals through the Internet is generally considered risky. In August 2009 the RCMP seized over 15,000 counterfeit erectile dysfunction pills containing irregular dosages and unadvertised ingredients and additives, all intended for online sale. Following the seizure, Health Canada issued a reminder about the risks of purchasing drugs online: "If you order from these sites, you may get counterfeit drugs that may contain the incorrect dose, the wrong ingredients, dangerous additives, or no active ingredients at all, which could result in potentially serious health risks." [WTR](#)

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