



# Drug, Food and Device Regulation in Canada 2008: The Year in Review

By Gordon S. Jepson

The year 2008 saw significant upheaval in the usually staid Canadian regulatory environment.<sup>1</sup> This article sets out the most significant changes of which regulatory affairs professionals should be aware.

## **Legislative Renewal**

In order to understand the crop of 2008 changes, we need to go back nearly a decade. There is a long-term project, emanating from Health Canada but until recently without significant political support, to revamp and consolidate most of Canada's federal food, drug, medical device, cosmetic, natural health product (dietary supplement) and related laws administered by the agency.<sup>2</sup> Initially, in 1998, it was hoped one

consolidated piece of legislation could be passed, perhaps to be called the *Canada Health Protection Act*, to replace the *Food and Drugs Act*, the *Quarantine Act*, the *Hazardous Products Act* and the *Radiation Emitting Devices Act*. The new act would have formally incorporated risk management principles into the system, added new offenses of tampering and deception, and extended postmarket surveillance.

This did not happen, but parts of the plan live on. In 2006, Health Canada released its so-called “Blueprint for Renewal.” In 2007, “Blueprint for Renewal II” was released. Together, these documents set out Health Canada’s goals for the system:

- develop a “lifecycle” regulatory approach to health products that would encompass all stages of product development and use (part of progressive licensing)
- develop a more transparent and consistent system of categorizing products and assessing their risks
- design and implement a more responsive food regulatory framework that protects and promotes human health, responds to emerging food safety and nutrition challenges, and minimizes unnecessary delays in bringing safe food and food products to the Canadian marketplace
- move away from a reactive “waiting for events” regulatory system and develop a more proactive approach
- better generate, disseminate and respond to safety and effectiveness data for health products and food, and develop a more proactive, postmarket evaluation strategy
- strengthen leadership on a range of health and safety issues affecting specific populations
- promote a more open and transparent regulatory system
- better synchronize the regulatory system with the objectives, policies and practices of the healthcare and innovation systems
- implement better legislative, regulatory and policy tools to improve compliance and enforcement
- work with partners in the healthcare system to make more and better information available about health products and food to enable Canadians to make informed decisions about their health

Aspects of this list have already been implemented; others are seemingly imminent. Those that have actually come into existence, or seem about to, are set out below.

### **Progressive Licensing Project**

The current approval process for drug products in Canada is based upon the concept of pre-market approval at a single point in time, i.e., when the drug’s Notice of Compliance (NOC) is issued. This has disadvantages both for the encouragement of early stage drugs, and in provisions for monitoring issues that arise with already-approved drugs. The latter consideration has, of course, been much in the public eye with the withdrawal of significant drugs due to unanticipated side effects.

The solution is seen as progressive drug licensing, which would be more of a lifecycle approach. This would include new policies or provisions possibly covering:

- early access to unapproved drugs where needed
- enhanced enforcement powers
- mandatory riskmanagement plans and pharmacovigilance plans for new drugs
- postapproval sale and marketing conditions, which could change over time

The proposal has been drafted and is currently undergoing both internal and external consultations. A number of discussion papers were made available, with the public comment period slated to end, at the time of writing, on 31 October 2008. Following comment, the next steps are to prepare the actual regulatory proposal and pass it into law.

However, as can be seen from the survey of Bill C-51 set out below, some of the proposals in the Progressive Licensing Project appear to have been incorporated into that somewhat reactive law, especially those regarding enhanced enforcement powers (including penalties) and postmarket surveillance. It remains to be seen how the full version of progressive licensing will play out in Canada.

### **Follow-On Biologics**

Health Canada took its first steps toward providing a regulatory approval pathway for follow-on biologics, or subsequent entry biologics (SEBs) in Health Canada’s terminology, in March 2008, when it released draft guidance addressing the information and submission requirements for SEBs. SEBs are biologics that enter the market

subsequent to, and are similar to, approved innovator biologics.

According to the draft guidance, Health Canada plans to amend the *Food and Drug Regulations* to provide a legal basis for the approval of SEBs. A new drug submission pathway will be created to enable approval based upon demonstrated similarity to an innovator reference product. In the interim, Health Canada believes the current approval process for biologics affords the appropriate flexibility for SEB approval.

The guidance clearly states that SEBs are not biogenics, and that the approval of a biologic through the proposed SEB pathway does not mean that the SEB may be automatically substituted for its reference biologic. However, the draft guidance contemplates the creation of a mechanism whereby substitutability may be granted “separate from and/or subsequent to market authorization of a SEB,” suggesting that a true “generic” biologic pathway may be created. The draft also holds that no new forms of patent or data protection will be afforded to innovator biologics, which will be given the same protection innovator small molecule drugs receive under the *Patent Act*, *Food and Drug Regulations* (Data Protection) and *Patented Medicines (Notice of Compliance) Regulations*.

A stakeholder consultation meeting was held to discuss the draft guidance and a summary report of those proceedings has been released to the public. Health Canada intends to release additional class-specific guidance documents that will provide specific information about the data required to establish similarity for certain classes of SEBs.

### Changes to Schedule A

On 26 December 2007, Health Canada published amendments to the *Food and Drugs Act*, *Food and Drug Regulations*, *Medical Device Regulations* and *Natural Health Product Regulations*, which changed allowable claims for those health products that may be advertised in Canada. (As has always been the case, prescription drugs are not permitted to be advertised to the public in Canada; see below.)

Schedule A is a list of diseases, disorders and abnormal physical states that has been appended to the *Food and Drugs Act* since its initial passage in 1934. These diseases and conditions are considered too serious for self-diagnosis and treatment. As a result, the *Food and Drugs Act* has always provided, at Section 3(2), that no one may advertise to the general public a food, drug,

cosmetic or device for any of the items listed on Schedule A.

After many years of lobbying, the list was finally modernized by the regulatory change appearing in *Canada Gazette Part II* (SOR/2007-288) of 13 December 2007. The most important change is that claims to prevent the diseases and conditions listed in Schedule A will now be permitted for over-the-counter (OTC) drugs and natural health products. Claims to prevent Schedule A diseases remain prohibited for medical devices, cosmetics and foods. Claims to treat or cure these diseases and conditions remain prohibited.

Simultaneously, by SOR/2007-289, certain amendments were made to modernize Schedule A itself (the *Food and Drugs Act* permits the modification of its schedules by regulation) by removing conditions with antique names, adding and deleting certain other conditions, and restricting the prohibition to the acute form of certain other conditions.

As a result, OTC drug and natural health product manufacturers in Canada are now permitted to make more preventative claims, and a broader range of claims, without running afoul of the prohibition in *Food and Drugs Act Section 3(2)* regarding Schedule A.

### Court Challenges to DTC Advertising Ban

As noted above, the Canadian *Food and Drugs Act* includes a blanket prohibition on the advertising of prescription drugs to the public. For many years, this ban has been weakened and flouted in Canada by certain advertisers. Also, most Canadians are exposed to US direct-to-consumer (DTC) advertising (through US radio and television broadcasts and magazines). As a result, Health Canada has resisted taking action against US prescription drug DTC advertising imported into Canada.

In response to the fact that US-based advertisements access the Canadian market but Canadian carriers are denied the revenue from such advertising, Canwest, a large Canadian media group that controls several radio and TV networks, commenced an action for a declaration that the provisions of the act and regulations prohibiting direct-to-consumer advertising of prescription drugs are unconstitutional.

Taking a different approach, Canwest later filed an application for judicial review in the Federal Court of Canada, seeking an order requiring the minister of health to investigate and

prosecute breaches of Canadian legislation by US entities (in many cases, its competitors).

While the original freedom of speech argument is still before the court, and may have been heard by the time this article is in print, in regard to the judicial review application, the Federal Court ruled in 2007 that Canwest had no standing to bring the application as it had no direct interest in the outcome of the application. Canwest appealed the decision; however, its appeal was dismissed by the Federal Court of Appeal in June 2008.<sup>3</sup>

## Proposed Legislation

The Conservative government of Prime Minister Stephen Harper introduced several significant proposed bills in 2008. With the calling of a Canadian federal election for 14 October 2008, these bills “died on the order paper,” i.e., were not passed. However, as the Conservatives won the election, the bills will likely be reintroduced. For the purposes of this article, these bills are described as though they will be passed in, essentially, their pre-election form.

In December 2007, the Canadian government unveiled “Canada’s Food and Consumer Safety Action Plan,” which contained initiatives to modernize the regulatory process for food, health and consumer products. Specifically, the action plan called for improvements in prevention, oversight and response to problems with food, health and consumer products that pose dangers to the health and safety of Canadians. Clearly, the motivation for these proposed changes were recent, highly-publicized imported drug and food quality issues in the US and Canada. On 8 April 2008, two bills were tabled in Parliament: Bill C-51, *An Act to amend the Food and Drugs Act and to make consequential amendments to other Acts*, and Bill C-52, *An Act respecting the safety of consumer products*. The proposed legislation aimed to modernize the *Food and Drugs Act* and carry out the action plan mandate. If passed in their current form, the amendments would represent substantial changes to the Canadian food and drug regulatory landscape, most importantly by substantially delegating regulatory rule-making authority from Parliament to Health Canada.

### **Bill C-51—Proposed Amendments to the Food and Drugs Act**

Bill C-51 stated that the legislative purpose of the *Food and Drugs Act* was “to protect and promote the health and safety of the public and encourage

accurate and consistent product representation by prohibiting and regulating certain activities in relation to foods, therapeutic products and cosmetics.” Currently, the *Food and Drugs Act* applies to the regulation of food, drugs, cosmetics and therapeutic devices. Bill C-51 proposed replacing references to the term “drugs” and “therapeutic devices” with the term “therapeutic products.” Accordingly, it is proposed that the act apply to “...foods, therapeutic products and cosmetics,” resulting in broader application of the act. After industry pressure, the government proposed an amendment to the bill for the creation of a separate category for natural health products within “therapeutic products,” rather than as a subset of drugs.

Bill C-51 broadened the list of prohibited activities regarding foods, therapeutic products or cosmetics considered a danger to human health or safety, including tampering, communicating false or misleading information, engaging in certain activities without the required authorization or license, and deceptive practices. A significant change proposed by Bill C-51 was the requirement to obtain authorizations or licenses from the minister of health (i.e., Health Canada) to engage in certain activities relating to the importation and sale of food or therapeutic products (food or marketing authorization), or to engage in certain activities at a specified premises (establishment license). Bill C-51 granted broad oversight powers to the minister of health regarding clinical trials, subject to already required clinical trial authorizations. Additionally, rather than restricting the advertisement of drugs by listing such drugs in schedules, Bill C-51 proposed prohibiting therapeutic advertising without market authorization unless designated by the regulations. The proposed amendments would provide the minister of health with the powers to request disclosure of information, disclose information to the public, disclose personal or confidential business information in certain circumstances and establish adverse event reporting for healthcare institutions. Bill C-51 also proposed broadening and strengthening inspection powers, permitting the minister of health to apply for an injunction and increasing penalties for contravening the act.<sup>4</sup>

### **Bill C-52—Proposed Consumer Product Safety Act**

The proposed *Consumer Product Safety Act* (CPSA) was intended to replace Part I of the *Hazardous Products Act*. The CPSA’s legislative purpose “is to protect the public by addressing

or preventing dangers to human health or safety that are posed by consumer products in Canada, including those that circulate within Canada and those that are imported.” The *CPSA* would apply to “consumer products,” which means “a product, including its components, parts or accessories that can reasonably be expected to be obtained by an individual to be used for non-commercial purposes, including for domestic, recreational and sports purposes, and includes its packaging.”

The *CPSA* introduced prohibitions against the manufacture, importation, advertisement or sale of consumer products that are a danger to human health or safety, including the communication of false or misleading information. Currently, the list of prohibited products under Part I, Schedule I of the *Hazardous Products Act* is more extensive than the proposed prohibited products under Schedule 2 of the *CPSA*. Since the *CPSA* would repeal Part I, Schedule I of the *Hazardous Products Act*, it is unclear whether the products excluded from Schedule 2 of the *CPSA* would continue to be prohibited. The *CPSA* also would impose increased record-keeping and reporting obligations on a manufacturer, importer or seller regarding a product’s source and sale, and establish an adverse event reporting system. The proposed *CPSA* included greater inspections powers, broad powers regarding disclosure of personal and business information, and increased penalties for contravention of the *CPSA*.

### **Patented Medicine (Notice of Compliance) Regulations**

Canada’s equivalent to the US *Hatch-Waxman Act* for generic drugs continued to evolve during the year and was subject to extensive consideration by the courts. Out of the many cases in 2008, at the time this article was being written, the most significant were:

*Pfizer Canada Inc. v. Canada (Health)*,  
2008 FCA 108

The Federal Court of Appeal clarified that a higher level of disclosure is not required to satisfy the disclosure requirement for selection patents. The lower court was found to have erred in focusing its sufficiency analysis on whether the data substantiates the promise made by the patent. Rather, the data are relevant to an analysis of a patent’s utility, novelty and/or obviousness.

*Nycomed Canada Inc. v. Novopharm Limited*,  
2008 FC 454

A prohibition application under the *Patented Medicines (Notice of Compliance) (PM(NOC)) Regulations* against Novopharm was summarily dismissed on the basis that it was an abuse of process for Nycomed to pursue the same claim of infringement against a second generic when it had previously lost on the same allegation against a previous generic involving the same patents and same factual nexus.

*Pfizer Canada Inc. v. Canada (Health) and Pharmascience*, 2008 FC 500

A judge precluded a generic drug company, Pharmascience, from asserting obviousness challenges to a patent because of an earlier decision on this issue involving a different generic, but the same patent. The judge applied the Federal Court of Appeal’s decision that relitigation in the context of NOC proceedings involving the same patent, even if different generics are involved, is not to be permitted unless a subsequent party is apprised of “better evidence or a more appropriate legal argument.”

*Lundbeck Canada Inc. v. Ratiopharm Inc.*  
2008 FC 579

The court issued the first decision pursuant to a Practice Direction of the Federal Court of Canada (made effective 7 January 2008) partially reversing the order in which the generic and brand companies submit their evidence in a PM(NOC) proceeding. The order of evidence was reversed on issues of invalidity on the basis that it would more likely than not lead to the just, most expeditious and least expensive determination of the underlying application on its merits.

*Apotex Inc. v. Canada (Health)*, 2008 FC 475

The Federal Court of Canada held that the minister of health was correct in deciding that Apotex could not avoid the requirements of serving a Notice of Allegation to address a patent listed on the patent register for COVERSYL 2 mg and 4 mg tablets by conducting bioequivalence studies using a different strength of the product (8 mg) than that for which the patent was listed. The minister had decided that Apotex must address the patent listed for the COVERSYL 2 mg and 4 mg tablets because an Abbreviated New Drug Submission (equivalent to a US Abbreviated New Drug Application), under section C.08.002.1 of the *Food and Drug Regulations* requires inclusion of a comparison

with a Canadian reference product for the purpose of demonstrating bioequivalence. This is sufficient to trigger the application of subsection 5(1) of the *PM(NOC) Regulations* requiring the patent listed against COVERSYL 2 mg and 4 mg tablets to be addressed.

## Medical Devices

The Medical Devices Bureau of Health Canada introduced a number of new guidance documents in 2008, including draft guidance documents for dealing with the changes to Schedule A of the *Food and Drugs Act* (see above) and information on Bis(2-ethylhexyl) phthalate (DEHP) and Bisphenol A (BPA) regarding medical devices sold in Canada.<sup>5</sup> There also was the release of a new list of recognized standards and the proposed Global Harmonization Task Force (GHTF) guideline entitled, *Quality management system—Medical devices—Guidance on the control of products and services obtained from suppliers*.<sup>6</sup>

## Natural Health Products

In Canada, natural health products (roughly equivalent to dietary supplements) are regulated as a subcategory of drugs, and require premarket approval from the Natural Health Products Directorate (NHPD) of Health Canada prior to sale.

In 2008, there continued to be a substantial backlog in the review of these premarket submissions, known as Product Licence Applications (PLAs). Thousands of applications are in queue without prospect of being reached, in some cases, for several years. Because of this backlog, the NHPD and the enforcement arm of Health Canada, the Health Products and Food Branch Inspectorate, continued their policy of allowing such products to be marketed, in most cases, while their submissions are pending review. The practical effect of this is that, once a PLA is filed, the product may be freely marketed in Canada pending approval. There does not seem to be much prospect of this situation changing in the short term, despite the lack of certainty it provides to both the public and the companies promoting these products.

The other significant development with regard to natural health products is the changes permitting claims to prevent Schedule A diseases, discussed more fully above.

## Conclusion

Primarily as a result of the reactions to recalls of imported products in 2007 and 2008 (contaminated Heparin, melamine in food products,

etc.), food and drug safety has moved much higher on the government agenda than at any time for many years. The result is Bills C-51 and C-52, which presumably will be reintroduced and passed in some form by the re-elected Conservative government. These bills in some ways move Health Canada's long-term agenda forward. At the same time, the relaxation on advertising of OTC drugs for Schedule A diseases is important, although unrelated. Along with the movement on progressive licensing and follow-on biologics, this has been a much busier year than usual for Canadian regulatory affairs. ■

## References

1. This article represents the situation as of the time of writing, in October of 2008.
2. For information on Canadian federal agencies other than Health Canada and their impact on drug and device regulation, see the author's article in the August 2007 issue of *Regulatory Affairs Focus*.
3. For more detail, see the article by Sue Diaz in the May 2008 issue of *Regulatory Focus*.
4. For a detailed discussion of Bills C-51 and C-52, please refer to our article "Proposed Legislation for the Regulation of Food, Health and Consumer Products in Canada" by the author and Lauren Lodenquai in the August 2008 issue of *Regulatory Focus*.
5. On 17 October 2008, the Canadian government announced that it would be drafting regulations to prohibit the importation, sale and advertising of polycarbonate baby bottles that contain BPA. The regulations apparently also will limit the amount of bisphenol A that is being released into the environment. Further, an additional \$1.7 million (Canadian) over the next three years has been allocated to fund research projects on BPA.
6. For more detail on the GHTF, see the article by Lauren Lodenquai in the June 2008 issue of *Regulatory Focus*.

## Author

**Gordon S. Jepson** is a partner in the Toronto law firm Deeth Williams Wall LLP, and a member of the Board of Editors for *Regulatory Focus*. He wishes to acknowledge the contributions of his colleagues Sue Diaz, Nick Wong, Michael Migus and Lauren Lodenquai to the preparation of this article. Jepson can be reached at [gjepson@dww.com](mailto:gjepson@dww.com).