

• CANADA PROPOSES AMENDMENTS TO ADVERSE DRUG REACTION REPORTING •

Eileen McMahon and Teresa Reguly
Torys LLP

On June 13, 2009, proposed regulations amending the *Food and Drug Regulations*¹ with respect to adverse drug reaction reporting (“Proposed Regulations”) were published in the *Canada Gazette*. The Proposed Regulations permit more rigorous monitoring of drug safety by the Minister of Health and bolster the Minister’s ability to enforce Canada’s reporting requirements for adverse drug reactions.²

Under the current regulations, manufacturers are required to submit a case report to the Minister within 15 days of becoming aware of any serious adverse drug reaction associated with a drug. Manufacturers must also prepare an annual summary of all adverse events associated with the drug, but there is no requirement to actually submit this summary to Health Canada *unless* it makes a determination (based on other information that it has gathered or that has been provided) that the drug may not be safe.

The Proposed Regulations will require manufacturers to determine, in preparing their annual summary report, whether a significant change has occurred in the risk-benefit profile of the drug since the last annual summary report. If the manufacturer concludes that a significant change has occurred, it must notify the Minister without delay. The Proposed Regulations will also allow the Minister to request annual summary reports and case reports if the Minister decides to examine the safety and effectiveness of the drug. Generally, the manufacturer must comply with this request within 30 days, but the Minister may set a shorter deadline if he or she has reasonable grounds to believe that the drug may pose a serious and imminent risk to human health.

The Proposed Regulations do not indicate whether the Minister will publish the manufacturer’s reports, or summaries thereof, on the Health Canada website. Presumably, the reports may be subject to access requests via the *Access to Information Act*³ regime.

In the United States, drug manufacturers must submit annual reports to the Food and Drug Administration (“FDA”) containing a “brief summary of significant new information from the previous year that might affect the safety, effectiveness, or labelling of the drug product”.⁴ This is quite different from the standard imposed by the Proposed Regulations. The amendment would require more frequent and timely reporting

in Canada (it is expected that an average of 10–15 reports would occur per year).

Note that there are proposed amendments to the U.S. regulations that would require manufacturers to notify the FDA of safety findings as they occur. If the Proposed Regulations come into force before any amendment to the U.S. regulations, there may be significant implications for the pharmaceutical industry. First, Health Canada may become aware of safety issues before the FDA does, and so may attempt to drive corrective action. Second, the fact that a Canadian manufacturer has reported a “significant change” in the risk-benefit profile may be alleged to be an admission regarding safety in the context of product liability litigation. This could spur class action suits regarding drugs that have been the subject of Canadian adverse event reports.

Stakeholders were invited to send written comments on the Proposed Regulations to Health Canada until August 12, 2009.

[Editors’ note: Eileen McMahon is the co-chair of Torys LLP’s Intellectual Property and Food and Drug Regulatory Practices. She is one of a handful of Canadian lawyers who advise on regulatory clearance and intellectual property protection of products, and is a registered patent and trademark agent in the United States and Canada.]

Teresa Reguly is a member of Torys LLP’s Intellectual Property Practice. Her practice focuses on intellectual property with an emphasis on advising clients with regulated products. She is a registered patent agent in Canada.]

¹ C.R.C., c. 870.

² Regulations Amending the Food and Drug Regulations (Adverse Drug Reaction Reporting), C. Gaz. 2009.I.1748.

³ R.S.C. 1985, c. A-1.

⁴ *Supra* note 2, at 1750.