Public disclosure of clinical trial results by Health Canada should be mandatory

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Health Canada is not prevented by law from publicly disclosing safety and efficacy data from clinical trials, pharmaceuticals, biologics and medical devices and should be more transparent, states an analysis in *CMAJ (Canadian Medical Association Journal)*.

An example of the need for transparency relates to antidepressants known as selective serotonin reuptake inhibitors (SSRIs). These were not authorized for sale to people under the age of 19 because of risks of self-harm associated with SSRIs in that age group. Health Canada did not disclose this evidence based on a legal stipulation that prevents disclosure of information that might be confidential or a "trade secret." Without full information on the risks, physicians were prescribing the drug to teenagers.

A combination of lack of action on the part of Health Canada, a drive to commercialize medical products and the adversarial nature of the legal system has prevented greater openness. Recent attempts by Health Canada to increase transparency during the "technical discussions on regulatory modernization" between October 2010 and January 2011 were countered by opposition from the associations of medical device, biotechnology and pharmaceutical companies.

There is also concern that regulators such as Health Canada are working with the industry, and this close relationship precludes openness.

"The court has noted that Health Canada's role as a regulator reduces

manufacturers' expectations of confidentiality, in contrast to other industry–government relations," writes Matthew Herder, Dalhousie University, Halifax, Nova Scotia. "The public interest, in other words, did not favour confidentiality."

To increase transparency, clinical trials should be registered, including design and key findings, although Health Canada has made little progress in this area. It should follow the lead of the US Food and Drug Administration to register clinical trials and disclose findings and make this mandatory under Canada's Food and Drugs Act.

"A lack of openness about designs and results of clinical trials, coupled with inadequate oversight of off-label use of drugs and adverse events, puts consumers of health products at risk," states the author.

"With Canadian Institutes of Health Research's recent misguided decision to withdraw its policy of clinical trials registration, Health Canada cannot continue to pass the buck," concludes Herder. "The law is no reason for further delay."

More information: Journal paper: www.cmaj.ca/lookup/doi/10.1503/cmaj.110721

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