Health Canada's new clinical trials database should be mandatory, says expert

Health Canada is populating a public database with limited information about approved drug trials but is not prepared to introduce a law requiring sponsors or researchers to register their trials. A leading industry critic, however, says a voluntary registry won't meet researchers' needs to evaluate the evidence.

Launched in May, the database includes the titles of trial protocols, the medical conditions involved, the drugs and populations being studied, enrolment status and the dates Health Canada authorized the trials. Although Health Canada has more information, including sites where patients are enrolled, it will inlcude only limited information.

Dr. Pat Stewart, interim senior executive director at Health Canada's Therapeutic Products Directorate, says the database "was meant to be something we could do in an efficient manner that would give enough high-level information, that if a patient was interested in finding out more, they could contact the sponsor and get more information."

The new database contains much less content than international clinical trial registries. Those registries also list study sites, investigators and their contact information, details of trial designs, primary and secondary outcome measures, and in some cases, trial results. That more comprehensive information allows academics assessing the risk and benefits of drugs to analyze all new drug studies, not just those that have been published.

But these trial registries rely on sponsors or researchers to list their studies — and not all of them do so. Health Canada is posting information it already has, Stewart points out, rather than relying on sponsors to list their trials. The agency conducted a public consultation about the database in late 2012 and early 2013, during which the pharmaceutical industry raised concerns about the amount of information in the database, citing proprietary issues.

Health Canada hopes the database will fill the information gap regarding clinical trials in Canada. In 2011–2012, when Health Canada surveyed two of the major international trial registries (clinicaltrials.gov and controlled-trials.com) it found that only about half the trials Health Canada approved had been registered.

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Trial registration is a legal requirement in the US and other jurisdictions, where failing to register a trial results in fines. In Canada, however, registration is voluntary.

This registration gap occurs despite the policy of major medical journals, who only publish the study results from trials that are registered. Since 2010, the Tri-Council Policy Statement, Canada's dominant ethical guideline concerning research on humans, has also required registration of all trials conducted in Canada.

"We have no authority to compel them to [register], and this is one of the reasons why we took steps to develop a clinical trials database," says Stewart.

Matthew Herder, an assistant professor at Dalhousie University in Halifax, Nova Scotia, who specializes in the commercialization of science, views the new database as "a very preliminary baby step." His concern is that the database does not require sponsors or researchers to register trials. Trial registration is a legal requirement in the US and other jurisdictions, where failing to register a trial results in fines. Herder would like to see Canada adopt the same model. Unless registries are mandatory, Herder says, researchers will be unable to evaluate the integrity of the evidence about any given drug.

Given widely reported scandals involving selective serotonin reuptake inhibitors and other drugs, where conclusions published in medical journals were later discovered to differ substantially from unpublished data, Herder believes it is past time for Health Canada to act.

"There have been major controversies about the evidence base behind medications which are approved, so I'm troubled that there hasn't been more headway made," he says.

Stewart believes the new database will help Canadians who are interested in finding experimental treatments. It may also prompt more discussion of mandatory trial registration.

But in other countries, the focus has shifted from registering trials to accessing trial results. In 2007, the US began requiring summary results of trials be reported within one year of completing data collection. This year, the *British Medical Journal* published information on its website about the problem of "hidden clinical trial data" (www.bmj.com/open-data). Author Ben Goldacre and others have also contributed to an online petition calling on governments, regulators and research organizations to ensure that all trials are registered and "the full methods and the results reported" (www.alltrials.net/). — Miriam Shuchman, Toronto, Ont.

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