

Postmarket drug surveillance network to be overseen by Canadian Institutes of Health Research

The Drug Safety and Effectiveness Network, promised by Prime Minister Stephen Harper in December 2007 and charged with the early identification of postmarket problems associated with prescription drugs, will be overseen by the Canadian Institutes of Health Research (CIHR).

The network, which is viewed as an integral component of Health Canada's shift to a "life-cycle" approach to drug regulation, will track the post-approval impact of certain drugs as they are used more widely, by more diverse types of patients and for longer periods (*CMAJ* 2008;179[5]:412-3 and *CMAJ* 2007;176[9]:1261-2).

The network's publicly funded research findings will be made available for policy- and decision-makers.

The aim is to "promote safe and effective use of pharmaceuticals by filling gaps in knowledge required to make effective evidence-based decisions about drugs," says Cynthia Sunstrum, manager of the Drug Safety and Effectiveness Network Project at Health Canada. The National Pharmaceutical Strategy had recommended that evaluation of real-world drug safety and effectiveness be strengthened.

After critics charged in 2008 that initial funding for the network was inadequate, the federal government earlier this year pledged \$32 million over 5 years for the initiative and \$10 million per year thereafter.

The network's research agenda will be established by a national oversight committee and funding will flow through the CIHR, which will be the coordinating body for a virtual network of linked research centres of excellence across the country.

Dr. David Henry, chief executive officer of the Institute for Clinical Evaluative Sciences in Toronto, Ontario,



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University researchers will be asked to conduct studies into the safety of drugs that are approved for marketing.

said in an email that while he has no concerns "in principle" with the CIHR's role with the network, it "must be truly independent and have the support for this right from the top of the CIHR."

The oversight committee, which will include representatives from drug regulators, drug plan managers, health professionals and patients, will set the research agenda and promote translation of the research findings into actions to safeguard the health of Canadians, says Diane Forbes, associate director for drug safety and effectiveness at CIHR.

Although several research organizations, such as the Institute for Clinical Evaluative Studies in Toronto, conduct research into the safety of drugs after they have been approved for marketing, no organization has had the mandate to conduct such research systematically

and to share findings widely.

The network will also develop international partnerships for sharing research and data.

Steve Morgan, associate director (training) for the Centre for Health Services and Policy Research at the University of British Columbia, in Vancouver, British Columbia, is on the advisory committee for the network. He says the network's first year funding of \$1 million is probably an appropriate amount for a start up, and will support small "catalyst" projects.

Once the network has "ramped up," it should be able to answer questions and solve problems posed by the oversight committee using approaches such as mining existing data sets, but also active surveillance and cohort trials, he says. Realistically, more money will need to be leveraged to finance costly "real work" trials.

The network's arm's-length position from Health Canada is important, since it will evaluate prescription drugs that have already been approved by the federal regulator, Morgan adds.

"Canadians, physicians and their patients need this independent research capability for answering important questions," says Noralou Roos, professor of community health sciences at the University of Manitoba in Winnipeg, Manitoba.

Roos, who spearheaded the Canadian Drug Policy Development Coalition, which, along with CIHR and Health Canada, led the push to create the network, adds that she is "delighted" with the long-term funding decision.

The funding was also welcomed by Women and Health Protection Central Coordinator Anne Rochon Ford. Statins "would be an excellent candidate for monitoring by this network," she says. — Ann Silversides, *CMAJ*

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