Former director general: Health Canada needs broader drug safety powers

Health Canada needs broader powers to assess the safety of new prescription drugs, including the power to require post-market trials, says the former director general of the department's Therapeutics Products Directorate.

"Drug safety has been brought into the spotlight once again . . . and we have to bring more structure" to this area, says Dr. Robert Peterson, a pediatrician who left Health Canada last year and is now director of the British Columbia Child and Youth Health Research Network.

International regulations adequately address drug safety about 75% of the time, Peterson told the University of British Columbia Centre for Health Services and Research Policy conference in February.

But important safety information does not surface for about 20% of drugs until after they are marketed and patients have begun taking them, he said. About 3 % of the time, new drugs have unexpected and catastrophic adverse effects on patients.

"Three percent is not acceptable," says Peterson.

All drugs have side effects and these side effects can't all be predicted on the basis of clinical trials, he said. "A large clinical trial would be 5000 [people], and a 1 in 10 000 adverse reaction would be obscured," he said.

The current regulatory framework has a "narrow focus on pre-market requirement," he told the Vancouver conference. Peterson wants to see requirements for post-market trials and provisional licensing of drugs, for the control of off-label use, and for more complete information for prescribers and patients.

Health Canada currently has no regulatory authority to control off-label use of drugs, Peterson said, which must be looked at "through the lens of drug safety."

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There are now no regulations governing post-market approval trials, which are in fact specifically exempt under Food and Drug Act regulations.

According to Health Canada, "some of the issues raised by Dr. Peterson are ones that Health Canada is looking at, primarily through a discussion on the modernization of our regulatory framework and through legislative renewal."

Similarly, there are now no regulations governing Phase 4 (post-market approval) trials, which are in fact specifically exempt under Food and Drug Act regulations, he told the conference.

But Phase 4 trials are frequently required to validate actual efficacy, especially when surrogate measures — instead of clinical outcomes — are used in Phase 3 trials, he noted.

The current voluntary system does not work. Despite promises made by pharmaceutical companies, "often these trials are not completed or even started . . . commitments are not being followed through."

Health Canada has no authority to compel changes to product labels after approval — with the exception of the "blunt instrument" of revoking market approval. And it does not require the provision to prescribers of strictly educational material about new drugs, he said. It is "absolutely absurd" to assume that product monographs can provide prescribers with a "distinctive competency" to prescribe, since monographs don't present information in an educational format. A monograph for a drug may state that regular tracking of liver function is important, but it won't explain why this might be highly important, he said.

Where there are substantial safety risks with a drug — for example, the antipsychotic clozapine — some useful educational material has been created, and Australia in particular has produced several model documents, he said. Prescribers and patients need more information about "what is known, and not known, about a drug."

Health Canada has only limited options for conditional release of a drug, whereas in Europe provisional authorization of a drug subject to yearly renewals is now possible, he said. This type of arrangement allows for clear limits on prescribing, regulated outcome reporting, and even a requirement for trials comparing a new drug to one already on the market.

Peterson also wants increased use of linked databases to track the use and

impact of drugs on patients. "Governments have walked away from drug development and left this to the commercial sector," he said. But by promoting data linkage and drug safety, governments can re-engage.

The former regulator acknowledged that changes to regulations take time, often several years. In the interim, he suggested that insurance companies or employers could make decisions about the conditions under which they would cover drug costs, addressing for example the off-label use of a drug.

Peterson worked for the changes he now advocates during his 5-year tenure at Health Canada. It was not frustration with the pace of change that led to his departure, he said. "But I also knew there were issues with a minority government and another election coming that might delay some of these changes." His decision to leave was also prompted by consideration of what he wanted to do with the remainder of his career.

Peterson continues his involvement with regulatory matters as chair of the regulatory advisory board of the UK-based Centre for Medicines Research International, he said. He is also a member of the Canadian Expert Drug Advisory Committee, which provides advice to the Common Drug Review. — Ann Silversides, Toronto

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Alberta leads country in e-health records

Talking to Dr. Tim Kolotyluk about cybermedicine is like running beside a freight train. You can't keep pace with his enthusiasm.

Kolotyluk, a 53-year-old family doctor in Westlock, just north of Edmonton, wired his clinic in 1998 knowing electronic health records were the way of the future. Today, Kolotyluk is one of 2899 Alberta physicians who have benefited from the Physician Office System Program (POSP), a government incentive to encourage office automation.

Kolotyluk and his 3 clinic colleagues have computers and printers in every examination room, 2 servers, voice recognition software, an information technology expert on call and a staff freed of paper files.

"You can no longer say, 'I don't like computers.' Our patients are leading the way with questions about the Internet," says Kolotyluk. "They have said, 'Come along with us.'"

The 5-year-old incentive program, which has cost taxpayers about $70 million so far, offers physicians up to $35 520 in monthly installments over 4 years, a sum intended to cover 70% of the cost of hardware, software and networking. Physicians are expected to pay the remaining 30%.

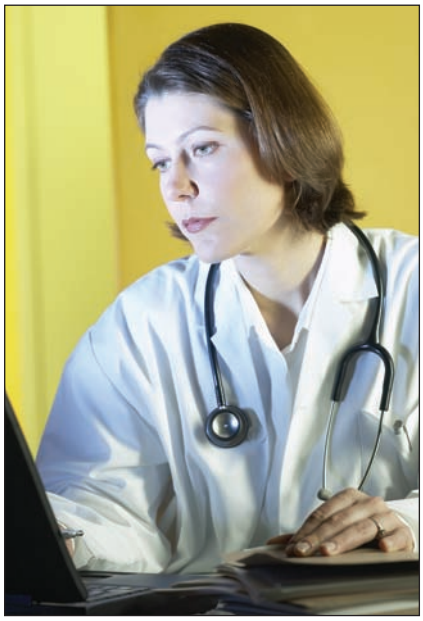
Roughly 53% of practising physicians have incorporated information technology into their practice in Alberta, the highest rate in Canada. Of those, more than 80% are currently using or converting to electronic medical records.

The Alberta Medical Association maintains doctors gave up about 1.5% in fee increases during contract talks in 2001 to designate money to the program. They could perhaps afford the sacrifice: Alberta physicians negotiated a 22% increase over 2 years in 2001, making them some of the highest paid medical professionals in the country at the time.

Oil-rich Alberta may have more discretionary spending than most provinces, but proponents say it's the innovative structure of the program, not just the dollars, that won converts — a structure they say required insightful leadership and compromise from physicians, government officials and, later, the health regions.

Dr. Fraser Armstrong, an Edmonton physician and co-chair of the AMA's POSP committee, explained the program's cornerstones:

- Vendor Conformance and Usability Requirements: a set of technical requirements against which technology vendors' products are conformance tested. Physicians must choose products that are VCUR-certified in order to get funding.
- Change management: The program provides management services through a network of private sector resources and physician mentors dedicated to helping physicians convert from paper to electronic records.
- Privacy Impact Assessment: Physicians are required to submit an assessment to the province's Information and Privacy Commissioner outlining how they plan to protect patient information.



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Roughly half of practising physicians have incorporated information technology into their practice in Alberta.

Armstrong is excited about the seemingly limitless opportunities computer technology affords doctors and patients: diagnostic tools that flag patient files for things like drug interactions, allergies and mammograms; efficient transfer of lab results and patient hospital reports; and easy access to complete patient files for clinic colleagues.

"I think we're stepping to a new level," he says. "We'll look at the patient differently than we ever have — more comprehensively."

The program has created a national buzz, especially in provinces struggling to establish electronic record-keeping. "Alberta has the best program I've seen and I've looked into the United States as well," says Bill Pascal, the Canadian Medical Association's chief technology