

Speed up drug-approval process, feds told

It's time for Ottawa to stand and deliver on its long-promised overhaul of the drug-review system and approval process so that Canadians can get readier access to new medicines, a coalition of consumer-based advocacy groups says.

Although former Health Minister Allan Rock embraced recommended reforms nearly 2 years ago, the department's record is actually getting worse, say the coauthors of the Canadians for Best Medicines Second National Summit on Reform of the Drug Review System, held in Aylmer, Que., in January.

Health Canada's stated target for drug approvals is 355 days, but it took an average of 743 days to review a drug in 2000, says Pat Kelly, chair of the Cancer Advocacy Coalition of Canada (see *CMAJ* 2000;162[4]:501-4). "That was 152 days longer than in 1999."

It took 985 days to approve the use of infliximab (Remicade) for the treatment of rheumatoid arthritis, adds Cheryl Koehn, summit cochair and founder of the health lobby group Arthritis Consumer Experts. "That's compared to 287 [days] in the United States."

Koehn and Kelly attribute the situation to a lack of political will to implement reforms recommended by a Health Canada working group in August 1999. At the first Best Medicines summit in May 2000, says Koehn, "Rock embraced the recommendations, but in the end have we gotten anywhere? Have any of them been implemented? No."

It's been estimated that an additional \$28 million a year is needed to provide the staffing that would allow Health Canada's Therapeutic Products Directorate to meet the 355-day target, Kelly notes. "Every single politician stands up at the podium and says 'the health of Canadians is my number-one priority,'" adds Koehn. "Well, prove it."

Koehn and Kelly hope the summit will help pressure the government to move immediately on the 29 measures recommended to promote timely access to drugs, improve postapproval surveillance, and make the system more transparent by providing more public participation.

Summit organizers say a more rapid harmonization of the Canadian, American and European drug-review systems is

needed so that conclusions drawn abroad can be adopted quickly here. "What value is added by having an independent review agency in Canada when so much of what it does is reliant on the FDA [US Food and Drug Administration] or the European Union or Australia?" Kelly asks.

"They're gathering data from a lot of other places other than Canada, so do we need to have a made-in-Canada stamp-of-approval on these new drugs that are coming onto market? Could we realize some efficiencies by looking at international harmonization?"

Following the summit, Koehn said a broad consensus had been reached to launch a campaign to press Ottawa to bolster funding for the drug-review process, including restoration of money clawed back from Health Canada because of its cost-recovery measures.

The coalition will also begin badgering MPs to account for the failure to fund the review process adequately. "We're going political," Koehn says. "We are taking this issue to the Hill and we will not rest until they put the money back." — *Wayne Kondro, Ottawa*

ON THE NET

Children and the environment

Physicians and parents need to appreciate and act on the fact that children are more vulnerable to potential environmental dangers than adults, the Canadian Association of Physicians for the

Environment (www.cape.ca) says. To help meet this need, CAPE has launched the Children's Environmental Health Project Web site (children.cape.ca), a primer and practical guide for physicians and other health care professionals.

"Children are not little adults," says Dr. Kapil Khatter, CAPE's executive director. "We know that, for many reasons, children have greater risk of exposure and harm compared with adults."

For instance, today's children will be exposed to more chemicals for longer periods than children from any previous generation. As well, their developing organs and tissues are more vulnerable to harm from exposure to toxic substances and they are unable to act on their own to avoid exposure.

The Web site concentrates on prevention and health promotion by studying chronic low-level exposure to a range

of potential environmental dangers, from chemical and metal pollutants to pesticides and tobacco smoke. Its key component is the instruction on taking an environmental history. "We explain why these questions are important and may raise red flags," says Khatter.

The Canadian Institute of Children's Health site (www.cich.ca) reports on ways to protect family health and features articles on potential links to health problems, and exposures to mould and various chemicals. The site also includes the Canadian Directory of Children's Environmental Health.

The multidisciplinary US Children's Environmental Health Network (www.cehn.org) provides extensive information and resources, including a resource guide and a training manual on pediatric environmental health. — *Barbara Sibbald, CMAJ*

