REPRODUCTIVE HEALTH

Nonprescription status for emergency contraception

Emergency contraception is slated to become available without a prescription in Canada by early April, but obtaining levonorgestrel (Plan B) will still require a consultation with a pharmacist (see Editorial, page 845). Proponents say the move is a good "first step," but are already looking to further increasing availability by having the drug available over the counter.

Ready availability of levonorgestrel is essential because the drug must be taken within 72 hours of unprotected intercourse (efficacy is greatest if taken within 24 hours). When a prescription is required accessibility can be problematic, especially on weekends and holidays.

After posting in Canada Gazette II, which is slated for early April, levonorgestrel (0.75 mg dosage) will be legally removed from Schedule F and available without a prescription. Provincial and territorial governments, which determine where a drug is sold, have decided levonorgestrel should be available behind the counter from pharmacists.

Levonorgestrel met all Health Canada's criteria for nonprescription medications, including safety, self-diagnosis and narrow therapeutic range. Levonorgestrel, the only approved emergency contraceptive (EC) in Canada, acts by preventing the release of an egg from the ovary, preventing fertilization of the egg or preventing the fertilized egg from attaching to the wall of the uterus. It has no effect on an established pregnancy.

The role of pharmacists "factored into our decision," says Health Canada's Brigitte Zirger. "The counselling is on the need for better contraception, not the drug itself," says the Director of the Policy Bureau in the Therapeutic Products Directorate.

Quebec, Saskatchewan and BC, which previously enacted legislation allowing pharmacists to prescribe the drug, insist on training.

The Canadian Pharmacists Association (CPhA) has various educational tools, including online training for pharmacists. The training is not compulsory, but is "strongly encouraged," says Senior Director, Professional Affairs Janet Cooper.

The move to nonprescription status came after a protracted lobbying effort by the Society of Obstetricians and Gynaecologists of Canada (SOGC), the CPhA, the Women's Health Network, the Royal College of Physicians and Surgeons of Canada and others.

While all these organizations are pleased to finally see increased availability, they also foresee some potential problems. Foremost is the fact that pharmacists can refuse to dispense the drug, which could impede access in areas with only 1 drug store.

Some pharmacists will undoubtedly refuse. Pharmacists for Life Canada, a pro-life lobby group, views EC as tantamount to abortion.

Dr. Sheila Dunn, medical director at Toronto's Bay Centre for Birth Control, views the behind-the-counter status as another "unnecessary barrier" to a "very safe medication." Dunn was part of the College's lobby effort and co-investigator in an Ontario pilot study of EC. She agrees that requiring pharmacist intervention is paternalistic. "If this was anything else, it would be available over the counter."

B. Sibbald

Planned Parenthood reports that the average EC user is 26 years old; about half have had a contraceptive accident, such as a broken condom.

That's the ultimate aim of the SOGC, which began lobbying for increased availability in 1998. "But we're extremely happy" with this "first step," says SOGC Associate Executive Vice President Dr. Vyta Senikas.

The change to nonprescription status also raises the question of whether jurisdictions will drop the drug from formularies, leaving women to foot the bill themselves, which could impede access. Plan B costs $30 in Ottawa pharmacies.

Meanwhile, the price may

DOI:10.1503/cmaj.050227

rise further as the CPhA lobbies to get pharmacists paid for their counselling service. Quebec and Saskatchewan already pay pharmacists about $16 per EC consultation — the same rate as a family physician.

"Access is still a big piece," says Madelaine Boscoe, director of the Canadian Women's Health Network. She sees a need for a broad awareness campaign and a database of pharmacists willing to distribute it as well as a rural distribution method, perhaps through clinics or nurses.

Comstock

Phamacists have the right to refuse to dispense emergency contraception, but "they have to ensure that the patient is cared for," says the pharmacists association.

Ultimately, "more access to EC means we are more able to prevent unintended pregnancies," says Linda Capperauld, ED of Planned Parenthood Canada. The CPhA reports that about 50% of all pregnancies are unintended, and of those, 50% are unwanted and half end in abortion. In 2000, over 105 000 abortions were performed in Canada. A UK study estimates that increased access to and awareness of EC could result in a halving of the abortion rate.

The new law means Plan B can now be advertised, says Mark Beaudet, at Paladin Labs Inc., the Canadian distributor. Ads will increase awareness and dispel misconceptions, such as the fact that it can be taken within 3 days of unprotected intercourse, not just the morning after.

Obtaining nonprescription status has been a long slog. After years of lobbying, Paladin, the SOGC, CPhA, the College and Women's Capital Corporation asked for priority review of an application to Health Canada. "This is the first time [priority] has been given for rescheduling a drug," says Cooper. There was an "unprecedented response" from some 300 groups.

"It's crazy that it's taken this long," says Boscoe of the Women's Health Network. "I wish Canada had shown more leadership."

The WHO includes EC on its list of essential medications. It is available without a prescription — and in some cases without a pharmacist's intervention — in 28 countries, including France, the UK, Denmark and Norway. Experiences in other countries indicate that easier access does not lead to excessive use. — *Barbara Sibbald*, CMAJ

HEALTH POLICY

Dosanjh to act on Canada Health Act violations

Published at www.cmaj.ca on Mar. 2, 2005.

Health Minister Ujjal Dosanjh will use a new dispute avoidance process when dealing with provinces accused of violating the Canada Health Act, the minister says.

"We want to make sure that we deal with these issues in a way that's amicable," Dosanjh told *CMAJ* in a Feb. 28 interview.

Health officials have been negotiating since last fall with BC and Quebec over allegations that the provinces are violating the Canada Health Act by permitting private surgeries to take place. In those provinces as well as in Alberta and Nova Scotia, other potential violations of the Act revolve around the existence of private MRI and other diagnostic clinics. A Canada Health Act issue dispute has also arisen in New Brunswick, which refuses to reimburse the cost of abortions carried out in private clinics.

During last September's First Ministers' meeting on health care, all of the provinces agreed to abide by a dispute avoidance and resolution (DAR) process first drawn up in 2002. Within the next couple of weeks, there will be an announcement about the results of the discussions with the provinces, Dosanjh said.

The process requires provinces and the federal government to exchange information and discuss potential breaches of the Act. When attempts to resolve a problem are unsuccessful, the federal or a provincial health minister can set a dispute resolution process in motion.

Within 60 days of a letter being sent, governments must muster their facts, prepare a report and begin negotiations. If those negotiations are unsuccessful, either minister can refer the dispute to a 3-person panel that will provide the federal health minister with recommendations within 60 days. Then it's up to the minister to make a decision.

"Ultimately, it's the minister's responsibility and discretion to penalize provinces, dollar for dollar, for any user fees [charged patients] or queue-jumping," Dosanjh said. "That's a decision I will make. But I want to make sure that we look at the DAR process and see if that can be used."

Providing more resources to the public health care system is the best way to deal with pressure for privatization of services, the minister said. Thanks to the $41 billion over 10 years that the federal government announced after the First Ministers' meeting, provinces now have the resources they need, he said.

"We do intend to enforce the Canada Health Act. There is no doubt in my mind about that." — *Laura Eggertson*, CMAJ

DOI:10.1503/cmaj.050243