Plan B comes out from behind the counter

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Canadian women will now be able to purchase the morning-after pill off the shelf.

Canada has become the fifth country in the world to approve the off-the-shelf sale of levonorgestrel (Plan B), the emergency contraception drug, after the National Association of Pharmacy Regulatory Authorities recommended it come out from behind the pharmacy counter.

"It's a good day for Canadian women," says Mark Beaudet, cofounder of Montréal-based Paladin Labs Inc., which licenses levonorgestrel in Canada. "Access is what this whole thing is about."

The change comes 3 years after Health Canada made levonorgestrel, also known as the morning-after pill, available without a prescription (*CMAJ* 2005;173[12]:1435-6).

However, prior to purchasing the drug, women had to consult with a pharmacist and provide sensitive personal information, such as the date of their last period and usual form of birth control.

This raised 2 privacy concerns: many pharmacies don't have private consulting rooms, and in some provinces, pharmacists recorded that information and stored it in patient files.

This latest change means women aren't obliged to receive counselling from the pharmacist prior to getting the drug.

The move may also mean that the cost of the drug, which Paladin Labs sells to pharmacies for about $16, will come down. It's currently sold for up to $50, which includes markup, and dispensing and counselling fees, the latter typically running at about $20. The Canadian Pharmacists Association says it is up to pharmacies to decide whether they will charge a counselling fee.

Selling levonorgestrel off-the-shelf should increase its availability for women who need it, says Dr. Sheila Dunn, medical director at Toronto's Bay Centre for Birth Control, who has studied women's access to emergency contraception (*CMAJ* 2008;178[4]:423-4). Cost is definitely a barrier to access, particularly for young women, and qualitative research suggests that privacy issues have been a barrier as well, she says.

"I don't think a pharmacist's assessment should be imposed on women who do not seek it out," says Dunn.

The scheduling change is not binding but most provinces and territories typically follow National Association of Pharmacy Regulatory Authorities recommendations, says Interim Executive Director Jim Dunsdon.

Ontario, Manitoba, New Brunswick and Nova Scotia are expected to act on the recommendation immediately, while Newfoundland, British Columbia and usually Saskatchewan require 6 weeks to 3 months to do so. Quebec is now a member of the association but it's unclear whether levonorgestrel will remain behind the counter. The picture in Alberta is also uncertain.

The National Association of Pharmacy Regulatory Authorities made its recommendations over the objections of the Canadian Pharmacy Association and the Canadian Association of Chain Drugstores, and despite the concerns of the Canadian Medical Association.

The pharmacy association says the consultations are important for women who may not need the medication or may require the opportunity to discuss birth control.

"There's a lot of misinformation and misconceptions and pharmacists see a fairly high number of women who actually think they need it and don't need it," says Janet Cooper, senior director of professional affairs. She estimates 25%–30% of women don't need the medication when they ask for it.

The Canadian Medical Association, meanwhile, asked the National Association of Pharmacy Regulatory Authorities not to change the drug's status until it had time to consult its members and was "surprised not to have been consulted," says Briane Scharfstein, associate secretary general for professional affairs. "We thought that counselling on a whole lot of issues related to sexual health was important for people who might be using emergency contraception."

The association also wanted to see any studies about whether moving the drug to non-prescription status in 2005 improved access, and had any negative effects on health, as well as requirements for counselling, follow-up and "appropriate contraception going forward."

Dunn, who conducted and published a study based on a pilot program allowing Ontario women to access levonorgestrel without a prescription (*JOGC* 2003;25:923-30), says her re-

search indicated 98% of women who came in and asked for the medication obtained it.

"In terms of identifying women's need for it, I think women do a pretty good job of it themselves," she says.

The Canadian Pharmacy Association acknowledges that even if women took levonorgestrel and didn't need it, it wouldn't cause them any harm.

The National Association of Pharmacy Regulatory Authorities arrived at its recommendation after a scientific advisory committee reviewed levonorgestrel and decided it met the evidence-based criteria for a Schedule III medication: it was safe, users could self-diagnose their condition, and the labelling and instructions were clear.

The drug, which prevents the release of an egg or prevents implantation of a fertilized egg within 72 hours of unprotected intercourse, will not affect an implanted egg or an established pregnancy. If taken within 24 hours of unprotected intercourse, it is 95% effective at preventing pregnancy.

"In the opinion of our expert committee, the safety profile of this is such that Schedule III was appropriate," says Dunsdon.

But the Canadian Pharmacy Association believes the decision should have been based on "social and other non-evidence-based aspects of drug scheduling," not just the safety of the molecule, says Cooper.

"We felt there was pretty strong evidence to show the value of the consultation with the pharmacist, but there is no evidence in terms of Schedule III improving outcomes for women."

The Canadian Pharmacy Association had asked the National Association of Pharmacy Regulatory Authorities to delay its decision about levonorgestrel until after it convened a task force to consider whether its scheduling decisions should be based on more than just science.

"We feel that the scheduling factors are too narrow, and dated, to consider all the patient care issues with emergency contraception. As such, we request that the National Association of Pharmacy Regulatory Authorities delay a decision until after the Task Force reports back, as it is important that such decisions are both evidence-based AND socially responsible," Cooper wrote in a May 14, 2008, letter to Dunsdon, a copy of which *CMAJ* obtained.

Although the National Association of Pharmacy Regulatory Authorities agreed to convene a task force, which is to report back on scheduling criteria by Nov. 2, 2008, it refused to delay the decision about levonorgestrel. "We didn't want to contaminate the process for Plan B," says Dunsdon. "The Plan B decision has been made based on current, evidence-based science."

Norway, the Netherlands, Sweden and India all dispense levonorgestrel over the counter without prescriptions. — Laura Eggertson, Ottawa, Ont.

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Canadian Nurses Association celebrates centennial

When a devastating earthquake heaved the Indian Ocean into a tsunami that killed or injured up to 500 000 people on Dec. 26, 2004, Indonesia was hit harder than any other country. The island nation, home to more than 230 million residents, lost an estimated 168 000 people.

The Canadian Nurses Association contacted the Indonesian National Nurses Association within 24 hours, offering financial, organizational and material support. The 2 nursing bodies had a pre-existing affiliation, which allowed for direct, easy communication. Association President Marlene Smadu says the relationship was a key factor in helping the Indonesian nurses to organize relief efforts, and accounts for their receptiveness to Canadian help.

The aid effort in Indonesia is indicative of the scope of the Canadian Nurses Association's reach. The Association, which celebrates its centennial this spring, is now the largest nursing body in Canada and world-renowned for its education, regulation and advocacy work.

Smadu calls the Association the "voice of registered nurses of Canada in promoting high-quality health and nursing care." It gives nurses international reach, inspiring many countries, like Indonesia, to turn their ears northwest for advice. It certifies nurses in various specialties and even delves into politics, turning nurses into activists and lobbyists who advocate for harm reduction and prevention-centered medicine as key components of high-quality, publicly funded, egalitarian health care.

Among topics addressed at its 2007 spring conference were demanding continued federal support for InSite, Vancouver's controversial supervised injection site for illegal drug users; working with environmental lobbyists to increase research into, and public awareness of, the environmental determinants of health; and campaigning for provincial governments to put money into a national program for the HPV vaccine Gardasil.

The association formed in 1908, the fourth national nursing body to join the International Council of Nurses. Originally called the Canadian National Association of Trained Nurses, it was made up of 16 organized nursing groups, but this number grew to 28 within 3 years. By 1924, the organizational structure had changed to a

Canadian Nurses Association

Mary Agnes Snively, the first president of the Canadian Nurses Association.