

Since the COX-2 withdrawals in 2003, the estimated number of filled prescriptions in Canada has plummeted from 7.3 million (worth about \$476 million) to 3.5 million (valued at about \$199 million) in 2005. — Barbara Sibbald, *CMAJ*

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Cervical cancer vaccine may come soon to Canada

A new vaccine against cervical cancer that could save hundreds of thousands of lives worldwide each year may soon be available in Canada.

Gardasil (quadrivalent human papillomavirus types 6, 11, 16, 18, recombinant vaccine) was approved in the US in June and could be offered there as early as September. Although Health Canada would not say if it will approve the vaccine, the drug's manufacturer, Merck Frosst, is confident Canadians will join other North Americans in having the world's first vaccine that protects against a risk factor for a cancer. Mexico approved the drug 1 week before the US.

In anticipation of Health Canada's approval, the National Advisory Committee on Immunization (NACI) has already started ironing out recommendations on who should get the vaccine, how it can best be delivered and other immunization practices.

"This is a great advancement for women's health," said Dr. Shelley Deeks, a medical epidemiologist and executive secretary of NACI. "We'll look at things like school leaving, like sexual debut data. All of those things will be taken into account when we make a recommendation."

Gardasil prevents infection from 2 genotypes of HPV — 16 and 18 — that cause 70% of cervical cancer. It also prevents infection from HPV 6 and 11, 2 genotypes that are the cause 90% of genital warts.

HPV is an extremely common sexually transmitted infection. In Canada,



Canapress

The vaccine is most effective when given before a person is sexually active. In the US, it's approved for females age 9 to 26.

about 75% of sexually active people will have at least 1 HPV infection in their lifetime. However, most people never know they are infected and most infections resolve on their own. Yet virtually all cases of cervical cancer are linked to HPV. While relatively rare in Canada, due to widespread availability of Pap tests, cervical cancer kills about 370 Canadian women annually; another 1350 or so are diagnosed with it each year.

This pales in comparison to the death toll in developing countries where cervical cancer kills about 240 000 women a year. The World Health Organization predicts that mortality rates could rise by almost 25% over the next 10 years and views the HPV vaccine as a major public health advance.

"WHO is very interested in this development and has an active collaboration with PATH [Program for Appropriate Technology in Health] to accelerate introduction of HPV vaccine in the developing world," said Dr. Marie-Paule Kieny, WHO's Director, Initiative for Vaccine Research, in an interview from Geneva, Switzerland.

Right now, several obstacles prevent WHO from including the HPV vaccine in its essential medicines list, added

Kieny, including the vaccine's short supply and high cost.

The vaccine costs US\$370 for a full 3-shot course given over 6 months. US sales could top \$1 billion; Canadian sales could total \$100 million a year.

Ironically, what is being heralded as a medical triumph by many is also rife with controversy infused in the politics of teen sex. Gardasil prevents HPV but does not treat it, so the vaccine is most effective when given before a person has sex. For the vast majority of women the vaccine's debut comes too late and regular Pap tests remain essential. The FDA has approved it for use in girls and women age 9 to 26. Some conservative groups in the US have opposed making the vaccine mandatory, arguing that parents should decide whether their children get vaccinated. Another concern is that the vaccine could give girls the wrong message that sex is safe. The more sex partners a person has, the greater the risk of an HPV infection.

A further complication could arise from Gardasil's limited demonstrated efficacy. Long term studies now underway should indicate whether booster shots will be required. — Alicia Priest, Victoria

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