



NEWS.scotsman.com

Sunday, 2nd November 2008

Expert's fear over cervical cancer vaccine



UK regulators and leading medics insist Cervarix is safe



Published Date: 02 November 2008

By Siobhan McFadyen and Kate Foster

MASS vaccination of Scottish schoolgirls against cervical cancer should have been delayed because not enough is known about possible side effects, a leading researcher claimed last night.

Dr Diane Harper, one of the world's leading experts in the field, said safety trials of the Cervarix vaccine should have been conducted for at least four more years before the decision was taken to give the jabs to thousands of girls in schools.

Harper concedes that Cervarix is effective against the HPV virus that causes many cases of cervical cancer and admits there is no evidence so far of any serious side effects. Manufacturer GlaxoSmithKline says rigorous tests have been conducted over six years.

But Harper believes the safety tests for side effects should have been conducted for at least a decade and doses given to millions of individuals around the world before any mass vaccination began. She described the cervical cancer vaccination scheme in Scotland as an "experiment".

Last night, UK regulators and leading medics insisted Cervarix was safe and that it could save hundreds of lives by preventing many cases of cervical cancer.

Two months ago the Scottish Government launched its £64m Human Papilloma Virus (HPV) vaccination programme in schools, aimed at vaccinating around 30,000 girls aged 12-13 every year. Around the country thousands of girls are currently being vaccinated every week.

The vaccine was approved by the European Medicines Agency in September 2007.

Harper, director of the Gynecologic Cancer Prevention Research Group at Dartmouth Medical Centre in the US, was herself paid by Glaxo to help conduct safety trials. She told Scotland on Sunday: "We can't tell you it's 100% safe because we don't know that. I think we would have been better waiting.

"In five years it will be pretty clear how safe it is because 70% of adverse events occur within five years and almost all of them, 97%, within 10 years. That way you have a good sense of comfort and you can reassure your population."

Harper said she would encourage women to use the vaccine, but on a voluntary basis. Under the Scottish programme, girls are receiving the vaccine unless they decide not to. She said: "I think there's a lot of room for discussion about making it voluntary so that girls are not put under pressure to get it."

A total of 344 cases of suspected adverse reactions among girls receiving Cervarix have so far been reported to the Medicines and Healthcare products Regulatory Agency. The most common include pain and rashes, dizziness, headaches and vomiting.

Cervarix is currently undergoing evaluation by the US Food and Drug Administration and is expected to be approved next year. A spokeswoman for GlaxoSmithKline said: "Cervarix had to undergo rigorous testing with large numbers of people in numerous clinical studies. In clinical studies, Cervarix was found to be generally well tolerated."

A Department of Health spokesman said: "Both HPV vaccines have gone through very thorough testing as part of the licensing process. In properly conducted long-term safety studies, where HPV vaccines have been compared with a placebo, there were no differences in reported serious adverse events between the two groups.

"In the absence of any scientific evidence that points to safety concerns, it would be irresponsible to raise inappropriate fears over HPV vaccine safety."

Dr Stuart Scott, deputy chairman of the British Medical Association's Scottish GP Committee, said: "This cancer kills a number of women every year and, although there are no large population studies, it has been used for a number of years."

'Seize the opportunity to get protected'

HAZEL NUNN, health information manager for Cancer Research UK, writes: The

introduction of the cervical cancer vaccine for teenage girls in Scotland began this September. It's an exciting step in the fight against a disease which still affects nearly 300 Scots women each year.

Cervical cancer is one of the most common cancers in women under 35. But from now, all girls aged 12 and 13 will be offered the vaccine. Over the next few years this will be extended to include women and girls up to the age of 18. And research suggests that the vaccine will prevent 70% of cervical cancers.

Earlier research has shown that cervical cancer is linked to some strains of the Human Papilloma Virus (HPV). The vaccine has been developed to give protection against two of these strains of HPV. It's exciting that research into the basic causes of cervical cancer has led to a new way of preventing the disease, and that it's now freely available to girls in Scotland.

It's vital to remember that the vaccine will not completely wipe out cervical cancer because it does not protect against every type of HPV. Now and for the foreseeable future, it is vital that women go for cervical screening (the smear test) when they're invited. In Scotland, cervical screening is available every three years for women aged 20 to 60.

"Screening can prevent cervical cancer by detecting unusual changes in the cervix before cancer develops, and it saves around 5,000 lives in the UK each year. Our message is to take up the opportunity to get vaccinated."