

## Now 9-yr-old girls can use Cervarix for cancer

07 May 2013 | Regulatory | By BioSpectrum Bureau



**Singapore:** Cervarix has now been approved for use in females aged nine-to-25 years to prevent persistent infection, premalignant cervical lesions and cervical cancer caused by Human Papillomavirus (HPV) types 16 and 18 by the US FDA.

The recently approved label update also comprises new data from the HPV-008 Patricia (PApilloma Trial Cervical cancer in young Adults) trial, which showed Cervarix demonstrated 93 per cent protection against advanced pre-cancerous lesions (CIN3+). Protection against CIN3+, the immediate stage before invasive cervical cancer, is considered to be the most stringent evidence of cervical cancer prevention.

Furthermore, the local label will also include other important updates from study HPV-023 that has reported sustained protective efficacy for up to 9.4 years after the first dose of Cervarix. Since the risk of HPV exposure persists throughout a woman's sexual life, the duration of protection provided by vaccination is critical to the overall vaccine effectiveness.

Cervarix has been shown to be generally well-tolerated. An integrated safety analysis of approximately 45,000 doses of Cervarix administered to approximately 16,000 subjects aged nine-to-72 years old, from ethnically and geographically diverse backgrounds, has shown no clinically significant differences in serious adverse events in women vaccinated with Cervarix compared to the control group.

According to the WHO/ICO (Institut CatalÀ d'Oncologia) Information Centre on Human Papilloma Virus and Cervical Cancer, the prevalence of high grade lesions for HPV types 16 or 18 in Asia is 45 percent. Cervarix demonstrated 93 percent efficacy against advanced pre-cancerous lesions (CIN3+), which is higher than what is expected from a vaccine that only protected against HPV types 16 and 18.