



16 December 2013

FDA ADVISORY
No. **2013-065**

Subject: FDA-REGISTERED HUMAN PAPILLOMAVIRUS VACCINE FOR ADOLESCENT AND ADULT WOMEN IS SAFE AND EFFECTIVE FOR PREVENTION AND CONTROL AGAINST CERVICAL CANCER

Cervical cancer is the second most frequent cancer in women in the world and the third greatest cause of death from cancer in women. More than 270,000 women die from cervical cancer every year and more than 85% occur in developing countries, including the Philippines. In highly developed countries, reproductive health programmes are in place for women to be screened against cervical cancer, thus making most pre-cancerous lesions identifiable at an early stage for early treatment. Early diagnosis and treatment of pre-cancerous lesion prevent around 80% of the cases from becoming full-blown cervical cancers.

Cervical cancer is caused mainly by sexually acquired infection with certain types of human papillomavirus (HPV), a viral group of more than 100 types that are common worldwide. At least 13 types have been shown to be high risk cancer-causing type. Types 16 and 18 cause 70% of cervical cancers and pre-cancerous cervical lesions. There is also evidence linking HPV with cancers of the anus, vulva, vagina and penis. Majority of the estimated 530,000 new cases of cancer worldwide is through HPV infection.

Unlike developed countries with effective screening that will enable women to be screened for pre-cancerous cervical lesions, developing countries do not have a programme on this. More often than not, the disease is already identified when symptoms have already developed, such as irregular, vaginal bleeding between periods or after sexual intercourse, pain in the back, leg or pelvis, weight loss, loss of appetite, vaginal discomfort or odourous discharge, and swelling of a leg. Prognosis for late-stage treatment of cervical cancer may be poor, resulting to higher mortality rate among women in developing compared to those who are in the developing countries.

There is a safe and effective vaccine for both adolescent and adult women against acquiring HPV infection leading to the development of cervical cancer. HPV vaccination does not require any screening against HPV infection or pre-cancerous cervical lesions, but may be administered in adolescent and adult women.

The Department of Health (DOH) recommends a comprehensive approach to cervical cancer prevention and control using safe and effective HPV vaccines for girls aged 9 to 13 years and women. Aside from the use of FDA-registered vaccines, the public health





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intervention shall also consist of community education, social mobilization, screening and treatment. This DOH primary prevention efforts will be reinforced by warnings about tobacco use, which often starts during adolescence and which is an important risk factor for cervical and other forms of cancer, and responsible parenthood and reproductive health care, including male circumcision.

For more information and clarification, please contact us via info@fda.gov.ph.


KENNETH Y. HARTIGAN-GO, MD
Acting Director General

