



28 November 2013

FDA Advisory

No. 2013 - **2013-061**

**SUBJECT: PUBLIC WARNING ON COUNTERFEIT PURIFIED CHICK
EMBRYO CELL (RABIPUR) RABIES VACCINE**

The Food and Drug Administration together with Novartis Healthcare Philippines, Inc. have determined that there are illegally imported and unregistered Purified Chick Embryo Cell (Rabipur) Rabies Vaccine being offered for sale in vaccination clinics, drug establishments and outlets and internet websites.

A complaint sample of Rabipur Rabies Vaccine was collected at Tabuk City, the capital of province of Kalinga. Upon verification of the complaint sample's authenticity, it was confirmed to be counterfeit.

Rabies Vaccine is given to people who are at high risk of exposure to rabies or to a person after they have been exposed to rabies to activate their immunization against rabies. Vaccines are sensitive biological substances that can lose their potency and effectiveness if they are exposed to temperatures outside the temperature range of + 2 °C to + 8 °C or when exposed to light. Proper handling and storage should be exercised to assure product's safety, efficacy, and quality. However, there is no assurance of safety, efficacy and quality of counterfeit vaccines.

All drug establishments and outlets are hereby warned that importation, distribution, or sale of any unregistered drug product is subject to sanctions and penalties stipulated in Republic Act No. 3720, as amended by Republic Act No. 9711, otherwise known as the "Food and Drug Administration (FDA) Act of 2009" and Republic Act No. 8203, otherwise known as "Special Law on Counterfeit Drugs".

All health care providers and consumers are hereby advised to obtain and use only registered rabies vaccine from legitimate sources to prevent any serious outcome such as treatment failure which can lead to acute progression of the disease and eventually death.



The public is encouraged to report any unscrupulous distribution or sale of unregistered vaccines immediately to report@fda.gov.ph.

For more information and inquiries, please e-mail us at info@fda.gov.ph.



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