Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

17 November 2014

FDA Advisory No. 2014-082

SUBJECT: PRODUCT RECALL OF LOT SPECIFIC HEPATITIS A VACCINE (INACTIVATED, VIROSOME) 24 IU/0.5mL SOLUTION FOR IM INJECTION WITH BRAND NAME EPAXAL

This is to inform the public that Vizacarra Pharmaceutical, Incorporated is voluntarily recalling the impacted lots of Hepatitis A Vaccine (Inactivated, Virosome) 24 IU/0.5 mL solution for IM injection with brand name Epaxal and registration number BR-426 due to quality issue identified at the product manufacturer, Crucell Switzerland AG, manufacturing facility in Spain, wherein traces of iron oxide particles were confirmed being released from the stopper feeding station on the filling lines.

The details of the affected lots that were shipped to the Philippines are as follows:

LOT NUMBER	EXPIRY DATE
3000060.08	31 January 2015
3000144.03	30 June 2015
3000144.06	30 June 2015
3000502.02	29 February 2016
3000734.02	31 October 2016
3000734.04	31 October 2016

Hepatitis A Vaccine (Inactivated, Virosome) 24 IU/0.5 mL solution for IM injection (Epaxal) is used for active immunization against Hepatitis A from beginning one (1) year of age. This product is packed in a 0.5mL pre-filled glass syringe per box with one (1) 25G x 1" separate needle.

The affected product lots present safety risk and potential adverse health consequences. Therefore, distributors, retailers, hospitals, pharmacies, or clinics that have the affected lots of Hepatitis A Vaccine (Inactivated, Virosome) 24 IU/0.5 mL solution for IM injection (Epaxal) are instructed to discontinue further distribution, sale and use. All consumers are likewise advised not to purchase or use the affected products.

All field Food and Drug Regulation Officers are ordered to monitor the availability of the product lots in the market.

Consumers may contact Vizcarra Pharmaceutical, Incorporated at telephone number +632 524-5641 or e-mail us at info@fda.gov.ph for any questions or additional information regarding the recall.

Any adverse reaction experienced from the use of the aforementioned product lots should be reported immediately to FDA by visiting www.fda.gov.ph. Look for the downloadable suspected adverse reaction form at the industry corner, fill-out all of the required fields and send via e-mail at adr@fda.gov.ph.

ATTY. NICOLAS B. LUTERO III, CESO III
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