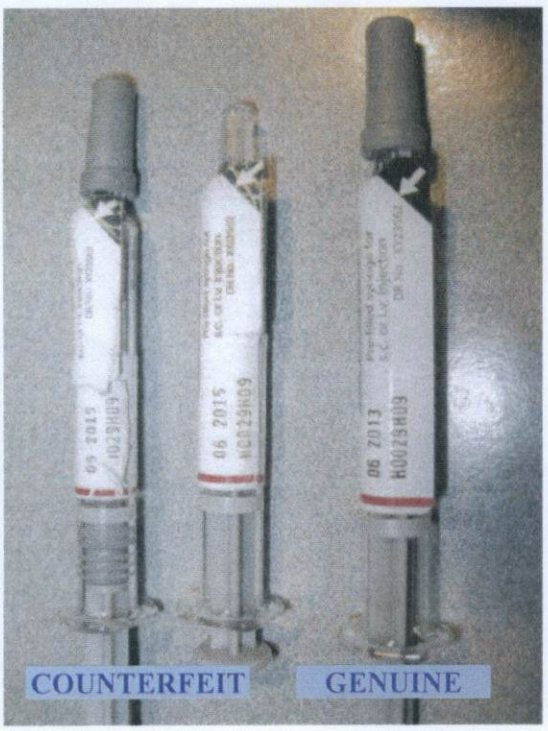
Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

21 November 2014

FDA Advisory No. 2014-085

SUBJECT: PUBLIC HEALTH WARNING AGAINST THE USE OF COUNTERFEITED EPOETIN BETA (RECORMON) 5,000 IU / 0.3 mL SOLUTION FOR INJECTION WITH BATCH No. H0029H09



The Food and Drug Administration (FDA) advises the public against the use of counterfeited Epoetin Beta (Recormon) 5,000 IU / 0.3mL Solution for Injection with batch number H0029H09.

The FDA was informed by Roche (Philippines), Inc. of the confirmed counterfeits of Epoetin Beta (Recormon) 5,000 IU / 0.3mL Solution for Injection with batch number H0029H09 found in Pampanga. The genuine product was manufactured by Roche Diagnostics GmBH – Mannheim, Germany, imported by Roche (Philippines), Inc. and distributed by Zuellig Pharma Corporation.

Roche (Philippines), Inc. noticed significant differences in printed information, printed description, color of the dosing bar, and perforation of the syringe label as compared to the genuine product. Major differences between the genuine and the counterfeit batch H0029H09 of Recormon product are as follows:

	GENUINE	COUNTERFEIT
LABEL	Made of plastic material which can be easily removed from the syringe body without residues.	Made of paper
EXPIRY DATE	06 2013 (June 2013)	06 2015 (June 2015)

Epoetin Beta (Recormon) 5,000 IU / 0.3mL Solution for Injection is used for the treatment of anemia associated with chronic renal failure. Epoetin Beta (Recormon) 5,000 IU / 0.3mL Solution for Injection is packed in a 0.3mL prefilled syringe with needle 27 G ½ (box of 6's).

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The FDA warns the public that the use of counterfeit products presents safety risks and adverse health consequences. All consumers are therefore advised to buy only from FDA-licensed drug outlets and pharmacies, and to demand official receipts.

All drug outlets and pharmacies are warned not to dispense, offer for sale or use counterfeited, unregistered or smuggled medicines that are peddled by unlicensed suppliers. Drug outlets and pharmacies should demand official receipts from distributors and check the Licenses to Operate of the supplier and the Certificate of Product Registration of the product they procure.

All FDA Field Regulatory Inspectors are ordered to remain vigilant in monitoring unregistered, counterfeited or smuggled medicines in the country and to seize counterfeited Epoetin Beta (Recormon) 5,000 IU / 0.3mL Solution for Injection with batch number H0029H09 from all outlets or establishments where they are found or offered for sale or use.

For more information and inquiries, please email us at info@fda.gov.ph. To report unregistered, counterfeited or smuggled medicines, kindly email us at report@fda.gov.ph

Any adverse reaction experienced from the use of any drug product 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.

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