Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

Food and Drug Administration
PHILIPPINES

25 June 2014

FDA Advisory
No. 2014-049

SUBJECT: PUBLIC WARNING ON ALL BATCHES OF HEPARIN SODIUM 1000 IU/ML AND 5000 IU/ML SOLUTION FOR INJECTION (IV/SC) WITH BRAND NAMES MEPARIN 5 AND MEPARIN 25 RESPECTIVELY

The FDA Philippines is advising all hospitals, health facilities and the public in general, to stop the use of Heparin Sodium 1000 IU/mL and 5000 IU/mL Solution for Injection with brand names Meparin 5 and Meparin 25 respectively manufactured by MedChem International, Ltd. - India, regardless of the batch. Likewise, this advisory extends to all government and commercial pharmacy to stop dispensing these particular drug products.

The FDA has determined the nature of the quality problem of Meparin 5 batch N-3176 and found contaminated with bacteria. Earlier, the FDA has issued a recall order on Meparin 5 batch N-3176 as per FDA Advisory No. 2014-047 and other batches of this product were put on quality hold as per FDA Advisory No. 2014-048. This advisory extends the quality hold on all batches of Meparin 25 in the interest of public health and safety. In effect, all batches of Meparin 5 and 25 should not be used or administered until further notice from this Office.

FDA will do tests on all parenteral products manufactured by MedChem International, Ltd. - India that are in the Philippine market.

Further, companies involved with this product who do not have a risk management plan should be required to monitor their own product's safety profile and to take rapid action when there is a probable cause on safety breaches. The accountability of companies in product quality and safety in this case is being studied by FDA with end in view for levying appropriate penalties.

The FDA enjoins medical professionals, administrators of the health facilities and the public to monitor FDA Philippines website for alerts, warnings and recalls.

Consumers may contact Pharma-Surrey International Inc. at telephone number +632 412 8364, or e-mail at pharmasurrey@yahoo.com. Consumers may also e-mail the FDA at info@fda.gov.ph for any questions or additional information regarding the product recall.

Any adverse reaction experienced from the aforementioned product should be reported immediately to FDA by visiting www.fda.gov.ph. Look for the ADR Report tab and proceed to fill-out all of the required fields.

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