Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

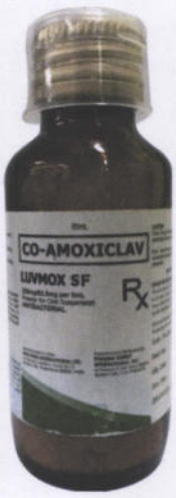
FDA ADVISORY
No. ~~2016~~-017

05 FEB 2016

SUBJECT: **Product Recall of Specific Batches of Co-Amoxiclav 250 mg/62.5 mg per 5mL Powder for Oral Suspension (Luvmox SF)**

The public is hereby warned by the Food and Drug Administration (FDA) that the affected batches of Co-Amoxiclav (Luvmox SF) 250 mg/62.5 mg per 5 mL Powder for Oral Suspension are being recalled from the market due to the failed results in the physical appearance and deliverable volume of the product batches as analyzed by the FDA Common Services Laboratory (CSL). The details of the product batches are as follows:

REGISTRATION NUMBER	**DR-XY41536**
BATCH NUMBER / EXPIRY DATE	**D-577 / FEBRUARY 2016** **D-578 / FEBRUARY 2016** **D-626 / SEPTEMBER 2016** **D-628 / SEPTEMBER 2016**
MANUFACTURER NAME AND ADDRESS	**MEDCHEM INTERNATIONAL LIMITED – A6 BANJARA GARDENS, RD. NO. 12 BANJARA HILLS HYDERABAD 500034, INDIA**
IMPORTER/DISTRIBUTOR (MAH)	**PHARMA-SURREY INTERNATIONAL, INC. – 46 BULUSAN ST., STA. MESA HEIGHTS, QUEZON CITY**



Co-Amoxiclav (Luvmox SF) 250 mg/62.5 mg per 5 mL Powder for Oral Suspension is used in the treatment of infections caused by susceptible bacterial strains producing Beta-lactamase in conditions such as otitis media, upper & lower respiratory-tract infections, skin & soft tissue infections, urinary-tract infections, genito-urinary & abdominal infections, severe dental infection with spreading cellulitis, animal bites, osteomyelitis, septicemia, peritonitis and post-operative infections. The product is packed in a 60 mL USP Type III Amber Glass Bottle in box of 1's.

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The affected product batches of Co-Amoxiclav (Luvmox SF) 250 mg/62.5 mg per 5 mL Powder for Oral Suspension present safety risks and potential adverse health consequences. Therefore, distributors, hospitals, retailers, pharmacies or clinics that have the affected batches of the drug product are instructed to discontinue further distribution, sale and use. All consumers are likewise advised not to purchase or use the affected product batches and may contact Pharma-Surrey International, Inc. at telephone number +632 412-8364 or mobile no. +63 915 9231737 or e-mail us at info@fda.gov.ph for any questions or additional information regarding the recall.

All Officers of the Field Regulatory Operations Office (FROO) are ordered to monitor the availability of the product batches in the market, appropriately seal discovered stocks of the affected batches of the product, and instruct the concerned establishment to return the sealed stocks to the Marketing Authorization Holder (MAH) for proper destruction to be witnessed by an appropriate FDA Representative.

Any suspected adverse reaction experienced from the use of the aforementioned product batches should be reported immediately to the FDA through this link: www.fda.gov.ph/adr-report-new and fill-out all of the required fields.

MARIA LOURDES C. SANTIAGO, MSc, MM
Officer-in-Charge, Director General

DTN: 20151110162215