



QSM/MC/IEA.112

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Information Exchange System

Levaquin (levofloxacin) injection (25 mg/ml 20 ml vials, Batch Nos. 6CB5W00, 6CB6100; Expiry February 2008): product likely intended for black market use; public health hazard

The Quality and Safety of Medicines team in WHO has received the following information from the Belgian Health Authorities:

According to Janssen Pharmaceutica NV, two batches of Levaquin injection 25mg/ml 20 ml vials have been sold in the United States of America as abandoned goods, after an extensive period on hold, awaiting US FDA approval for transfer to the wholesale site. The buyer has shipped the product to Israel, where the shipment was seized and secured by the Ministry of Health based on a request from Johnson & Johnson.

The Israeli Ministry of Health plans to release the goods to the buyer on Wednesday, 29 November 2006, the Ministry being under the false impression that the US FDA has condoned this sale and exportation to Israel.

Janssen Pharmaceutica warns that the product is only approved for use in the United States of America and in Latin America (Argentina, Paraguay, Uruguay, Venezuela, Brazil and Columbia), the product is labeled for sale only in the USA, the above mentioned batches of the product may not have been stored properly (15-25 °C, protected from light), they were obtained under suspicious circumstances and are intended for the black market.

Under these circumstances the product with these batch numbers, if allowed for use, could pose a serious safety hazard to public health.

This note is therefore being disseminated for the information of the Israeli Ministry of Health, for any preventive or follow up regulatory action, as appropriate.

Reference:

Electronic communication to WHO, HQ from the Office of the Federal Public Service (Health, Food Chain Safety and Environment), Belgium.