Drug Alert

CLASS 2 MEDICINES RECALL

Action Within 48 Hours

Date: 25 July 2013 Our Ref: MDR/ 04-07/13 - 3

Dear Healthcare Professional,

Metformin 500mg tablets

AA154/06501

WOCKHARDT UK LTD. (000154)

Batch Number	Expiry Date	Pack Size	First Distributed
DK11470	31 JUL 13	28 tablets	19/01/2011
DL10615	28 FEB 14	28 tablets	24/05/2012
DL10635	28 FEB 14	28 tablets	24/05/2012
DL10646	28 FEB 14	28 tablets	24/05/2012
DL10738	28 FEB 14	28 tablets	24/05/2012
DL10748	28 FEB 14	28 tablets	24/05/2012
DM11974	30 JUN 15	28 tablets	11/02/2013
DM11975	30 JUN 15	28 tablets	11/02/2013
DM12067	30 JUN 16	28 tablets	11/02/2013
DM12536	31 AUG 15	28 tablets	11/02/2013
DM12538	31 AUG 15	28 tablets	11/02/2013
DM12544	31 AUG 15	28 tablets	11/02/2013
DM12555	31 AUG 15	28 tablets	11/02/2013
DM12559	31 AUG 15	28 tablets	11/02/2013
DM12560	31 AUG 15	28 tablets	11/02/2013
DM12881	31 AUG 15	28 tablets	01/04/2013
DM12882	31 AUG 15	28 tablets	01/04/2013
DM12968	30 SEP 15	28 tablets	01/04/2013
DM12973	30 SEP 15	28 tablets	01/04/2013
DN10179	30 DEC 15	28 tablets	23/05/2013
DN10196	30 DEC 15	28 tablets	23/05/2013
DN10312	30 DEC 15	28 tablets	23/05/2013
DN10350	30 DEC 15	28 tablets	23/05/2013
DL12482	30 SEP 14	84 tablets	24/05/2012
DL12483	30 SEP 14	84 tablets	24/05/2012
DL12494	30 SEP 14	84 tablets	24/05/2012
DL12674	31 OCT 14	84 tablets	24/05/2012
DL12675	31 OCT 14	84 tablets	24/05/2012

DL12738	31 OCT 14	84 tablets	24/05/2012
DL12748	31 OCT 14	84 tablets	24/05/2012

Medicinal product pertaining to the above product and the above mentioned batches is being recalled up to pharmacy level as a precautionary measure by the local distributor representing the Marketing Authorisation Holder under the supervision of the Malta Medicines Authority. This recall is being affected following a routine inspection of the manufacturing site in India. The inspection identified deficiencies in good manufacturing practice (GMP) and the GMP certificate for this site has been withdrawn.

The product batches being recalled have been tested on importation into the EU and Qualified Person (QP) released. However it is considered that they have not been manufactured in line with GMP requirements.

All stock of these batches is to be immediately quarantined awaiting collection by the local distributor, who is providing alternative stock to ensure continued availability of the medicinal product.

Yours faithfully,

S Serge
Medicines Inspector