DRUG ALERT

CLASS 2 MEDICINES RECALL

Action Within 48 Hours
Pharmacy, Clinic and Wholesaler Level Recall

Date: 16 September 2013 EL (13)A/22 Our Ref: MDR 14-09/13

Dear Healthcare Professional,

Eli Lilly Nederland B.V.

BYDUREON 2mg powder and solvent for prolonged-release suspension for injection **EU/1/11/696/001**
(Exenatide)

Batch Number	Expiry Date	Pack Size	First Distributed
C164827	31 August 2015	4 x 1 single-dose kit (1 vial + 1 syringe)	12 July 2013

Bristol-Myers Squibb and Astra Zeneca, who, following a recent change of ownership, are now Marketing Authorisation holders for the Bydureon (Exenatide) product licence range, are recalling the above batch of Bydureon to pharmacy, clinic and wholesaler level, following an in-depth review of manufacturing records which indicated that this batch may contain a very small number of under filled vials. The low fills impact approximately 0.2% of the batch and range between 30% and 75% of the labeled dose.

Remaining stocks of the affected batch should be quarantined and returned to the original supplier for credit. For enquiries relating to stock returns please contact your original suppliers local service center.

For medical information enquiries please contact BMS by phone on 0800 731 1736 or by email to medical.information@bms.com.

Recipients of this Drug Alert should bring it to the attention of relevant contacts by copy of this letter. Local area teams are asked to forward this to relevant clinics, general practitioners and community pharmacists for information.

Yours faithfully

Alison Bunce
Pharmaceutical Assessor

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