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10 March 2011

IMMEDIATE MESSAGE TO:

1. Directors of Pharmacy
2. Chief Pharmacists NHS Boards
3. Hospital Pharmacy Managers
4. Medical Directors NHS Boards
5. Chief Executives NHS Boards

Dear Healthcare Professional,

DRUG ALERT NO 6 – CLASS 2

Please find attached revised drug safety information from the Medicines and Healthcare products Regulatory agency (MHRA) for onward transmission (see list below)

1. Please could all Directors of Pharmacy forward this alert to:-
 - Community Pharmacists
 - Hospital Pharmacists
 - Chief Pharmacists to forward on to Medicines Information Pharmacists
2. Please could Medical Directors forward this alert to:-
 - General Practitioners
 - Relevant Clinics
 - Chief Executives of NHS Boards

Thank you for your co-operation.

Yours sincerely

Leslie Smith

pp
IRENE FAZAKERLEY
Pharmacy Division

Safeguarding public health
Defective Medicines Report Centre
151 Buckingham Palace Road
London
SW1W 9SZ
Telephone +44 (0)20 3080 6574

MHRA

DRUG ALERT

CLASS 2 MEDICINES RECALL

Action Within 48 Hours PHARMACY LEVEL RECALL

Date: 10 March 2011

EL (11)A/06

Our Ref: MDR 26-02/11

Dear Healthcare Professional,

OPD Laboratories Limited / Caseview (PL) Ltd / Delta Pharma (Europe) Limited

Various Parallel Imported Products

Product	PLPI Number	PLPI Holder	Reason for recall
Aricept Evess 5mg Orodispersible Tablets	15814/0844	OPD	Failure to update Patient Information Leaflet to include updated information on administration and safety warnings
Aricept Evess 10mg Orodispersible Tablets	15814/0845	OPD	Failure to update Patient Information Leaflet to include updated information on administration and safety warnings.
Cytotec 200mcg Tablets	15814/0175	OPD	Failure to update patient Information Leaflet to include additional indications and safety warnings.
Nexium 20mg Tablets	13826/0739	Caseview	Failure to update Patient Information Leaflet (PIL). Indication which is specific to 40mg presentation not removed from PIL.
Pariet 10mg Gastro-Resistant Tablets	13826/1667	Caseview	Failure to update Patient Information leaflets to include updated information on administration and safety warnings
Pariet 20mg Gastro-Resistant Tablets	13826/1668	Caseview	Failure to update Patient Information leaflets to include updated information on administration and safety warnings
Seretide 250mcg Evohaler	15814/0750	OPD	Type size on the patient Information Leaflet is smaller than the minimum recommended and some patients may have difficulty reading it.
Serevent 25mcg Evohaler	15814/0875	OPD	Type size on the Patient Information Leaflet is smaller than the minimum recommended and some patients

MHRA Distribution:

Regional Contacts for NHS Trusts and Provider Units

Chief Pharmacists: England, Scotland, Wales, Northern Ireland

Prison Health Policy Unit (DH)

Chief Pharmacists: Jersey, Guernsey, Alderney, Sark, Isle of Man, Gibraltar

Special Hospitals

Healthcare Commission for distribution to Independent Health Care Establishments

Primary Care Trusts (England)

Medicines and Healthcare products Regulatory Agency (MHRA)

151 Buckingham Palace Road London SW1W 9SZ UK

T 020 3080 6000 www.mhra.gov.uk

An executive agency of the Department of Health

			may have difficulty reading it
Seroquel 100mg Tablets	15814/0748	OPD	Failure to update Patient Information Leaflet to include safety warnings, including warning on risk of venous thromboembolism which is mandatory and was initiated by the European Medicines Agency.
Seroquel 200mg Tablets	15814/0749	OPD	Failure to update Patient Information Leaflet to include safety warnings, including warning on risk of venous thromboembolism which is mandatory and was initiated by the European Medicines Agency.
Tanatril 5mg Tablets	17805/0387	Delta	Failure to update Patient Information Leaflets to include safety warnings including warning on use during pregnancy and lactation which is mandatory and was initiated by the European Medicines Agency.
Xatral XL	15814/0516	OPD	Marketing Authorisation (PLPI) cancelled in March 2009. All batches released since then are unlicensed.

All unexpired stock of the above products is being recalled due to issues with Patient Information Leaflets (PILs), as outlined in the table.

Pharmacists are asked to quarantine all unused stock and return it to the original wholesaler for credit. For further stock enquiries please contact Manish Shah on 01923 444999

Please note, all unexpired stock of the following products has already been recalled (Letter from Sigma Pharmaceuticals plc dated 10th February 2011) due to failures to update Patient Information leaflets:

Product	PLPI Number	PLPI Holder
Cozaar 50mg Tablets	15814/0728	OPD
Cozaar 50mg Tablets	15814/0729	OPD
Diovan 160mg Capsules*	15814/0625	OPD
Coversyl Arginine 5mg Tablets	15814/0910	OPD
Coversyl Arginine 10mg Tablets	15814/0911	OPD

*Information updated

Recipients of this Drug Alert should bring it to the attention of relevant contacts by copy of this letter. Primary Care Trusts are asked to forward this to General Practitioners, Community Pharmacists and relevant clinics.

Yours faithfully

Alison Bunce

Pharmaceutical Assessor, DMRC