Public Health Link

From the Chief Medical Officer for Wales

Distribution:	As Appendix 2
From:	Chief Pharmaceutical Officer, Andrew Evans
Date:	9 October 2019
Reference:	CEM/CPhA/2019/24
Category:	Class 2: Action within 48 hours
Title:	Drug Alert Class 2, Action Within 48 Hours, Glaxosmithkline Trading As Glaxo Welcome Uk Ltd, Zantac Injection 50mg/2ml, Zantac Syrup 150mg/10ml, Zantac Tablets 150mg, Zantac Tablets 300mg
For Action by:	General Practitioners Dispensing General Practitioners – please ensure this message is seen by all working in your dispensary and retain a copy in your 'locum information pack' Community Pharmacists Hospital pharmacies Chief Pharmacists
For Information:	See Annex 2 – Distribution List
What is this about:	Full details are set out below.
Why has it been sent:	For your information, action and to pass on to colleagues.

Issue:

GlaxoSmithKline is recalling all unexpired stock of Zantac (ranitidine hydrochloride) prescription only medicine (POM) from pharmacies as a precautionary measure due to possible contamination with an impurity N-nitrosodimethylamine (NDMA) which has genotoxic and carcinogenic potential.

Full details of the drug alert are included in the attached PDF file. Please forward to listed recipients. This information is also published on the MHRA website https://www.gov.uk/drug-device-alerts

Appendix 1

To: Chief Executives of Health Boards and NHS Trusts

To: Medical Directors of Health Boards

To: Nurse Directors Health Boards

To: Directors of Public Health

To: Hospital Principals and Chief Pharmacists to action as per alert

To: **NHS Wales Shared Services Partnership to forward to:**

General Practitioners

Dispensing General Practitioners

Community Pharmacists

Deputising services

HB Prescribing Advisers

Independent/Private clinics and Hospitals and Hospices throughout Wales

Medicines & Healthcare products Regulatory Agency

MHRA
Regulating Medicines and Medical Devices

DRUG ALERT

CLASS 2 MEDICINES RECALL

Action Within 48 Hours
Pharmacy Level Recall

Date: 08 October 2019 EL (19)A/24 Our Ref: MDR 56-09/19

Dear Healthcare Professional,

GlaxoSmithKline trading as Glaxo Welcome UK Ltd

Product	PL Number
Zantac Syrup 150mg/10ml	10949/0108
Zantac Injection 50mg/2ml	10949/0109
Zantac Tablets 150mg	10949/0042
Zantac Tablets 300mg	10949/0043

Generic Name: Ranitidine

GlaxoSmithKline is recalling all unexpired stock of the above products from pharmacies as a precautionary measure due to possible contamination with an impurity N-nitrosodimethylamine (NDMA) which has genotoxic and carcinogenic potential.

Advice for healthcare professionals

- Stop supplying the above products immediately. Quarantine all remaining stock and return it to your supplier using your supplier's approved process.
- If you receive queries about this issue from patients, advise them not to stop taking their medication as the health risk of discontinuing the medicine is higher than the potential risk presented by the contaminant. A treatment review is not necessary until the next routine appointment.

This is an on-going issue and the MHRA is actively involved with the European Medicines Agency and with other medicines regulators to determine any possible impact. An investigation into other potentially impacted products is continuing and further updates will be provided as the investigation progresses.

Company contacts for further information

For stock control enquiries please refer to https://gskpro.com/en-gb/ or contact 0800-221-441.

For medical information enquiries please contact ukmedinfo@gsk.com, via the Live Chat facility on https://hcp.gsk.co.uk/contact-us/live-chat.html or on 0800 221 441 (option 2).

Recipients of this Drug Alert should bring it to the attention of relevant contacts by copy of this letter.

NHS Regional teams are asked to forward this to relevant clinics, general practitioners and community pharmacists.

Yours faithfully

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