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Product Recall

Product Name	Licence Number	Batch No.
Zantac 150 mg Film-coated Tablets	PA1077/13/3	All in-date batches

3rd October 2019

Dear Wholesaler,

Further to GSK's recall letter of 24th September 2019, we wish to advise you that all in-date batches of the above-listed Zantac product is being recalled with immediate effect.

This recall is going to **pharmacy level**.

This action has been agreed with the Health Products Regulatory Authority

The reason for the recall is that a nitrosamine impurity has been identified in ranitidine active substance batches manufactured at a manufacturing site in India. Ranitidine active substance from that site was included in the above product. This impurity, N-Nitroso dimethylamine (NDMA), has been classified as a probable human carcinogen.

Please immediately quarantine any units of the above product which you have in your possession. Please also quarantine stock which you receive back from your pharmacy customers.

GSK will uplift quarantined stock. In order to arrange uplift, please provide the following details in spreadsheet format to gskpharmacs@prl.ie: SKU, product description, quantity and batch details (batch number and expiry date). GSK will generate an uplift document based on the data provided.

GSK will issue credit for uplifts which are arranged prior to the 15th November 2019.

If you have supplied the above product to any other wholesaler, please fax those wholesalers a copy of this recall letter, requesting that they quarantine and return any unsold quantities to you.

Please send an e-mail to ie.dublinquality@gsk.com confirming receipt of this communication.

Please note that GlaxoSmithKline (Ireland) Ltd. will only accept units that have been supplied by GlaxoSmithKline (Ireland) Ltd. All parallel imported units should be returned to the supplier they were sourced from.

Replacement stock of this product is not available to order.

Please note that, at this time, no additional batches of the intravenous and syrup presentations of Zantac have been included in this second recall action, on the basis that there is no evidence that the impurity has caused any harm to patients and that there are no immediate alternatives to these prescribed medicines. This is at the request of the Health Products Regulatory Authority (HPRA).

We apologise for any inconvenience this action may cause. Should you have any queries, please contact Bartosz Romanowski at telephone number 0876055816.

Yours sincerely,

Bartosz Romanowski
LOC Quality Manager & Responsible Person