"URGENT MEDICINE RECALL"

CLASS II / TYPE B

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Date: 02-10-2019

Dear Sir/Madam,

BATCH RECALL – ZANTAC INJECTION 50 mg/2 ml (reg. no.: S/11.4.3/277)
ZANTAC EFFERVESCENT 150 (reg. no.: Z/11.4.3/303)
ZANTAC SYRUP (reg. no.: W/11.4.3/277)

GlaxoSmithKline (GSK) in agreement with the South African Health Products Regulatory Authority (SAHPRA) is issuing a recall for **all batches of Zantac Injection 50 mg/2ml; Zantac Effervescent 150 and Zantac Syrup** in South Africa. Our records indicate that you may have inventory that is impacted by this recall.

In South Africa, the following products are affected.

Product	Reg. No.	Pack Size	Batch Number	Expiry Date
Zantac Injection 50 mg/2 ml	S/11.4.3/277	5 x 2 ml Ampoules	929K	27-Aug-2021
			V67R	19-Aug-2021
			H35R	15-Jun-2021
			356R	13-Apr-2021
			JR7C	14-Dec-2020
			B89U-A	Oct-2020
			SG4S	June-2020
			7M4G-A	Jan-2020
			7M4G	Jan-2020
			X816	Dec-2019
			X729	Dec-2019
			X728	Dec-2019
			Q600	Oct-2019
Zantac Effervescent 150 mg Tablets	Z/11.4.3/303	Tube of 15 Tablets	180011663	31-May-2020
			170019673	Sep-2019
Zantac Syrup 150 mg/10 ml	W/11.4.3/277	300 ml Amber Glass Bottle	B30819A	Jan-2021
			B58118C	31-Mar-2020
			B23517J	Oct-2019

South Africa
Reg No 1948/030135/07
Registered Office :
Flushing Meadows Building
The Campus
57 Sloane Street
Bryanston 2021

Background

- GSK has been contacted by Regulatory Authorities regarding the detection of genotoxic nitrosamine (NDMA) in Zantac (ranitidine) products.
- On 19 September 2019, Saraca Laboratories informed GSK that it had been notified by the European Directorate for the Quality of Medicines (EDQM) that its Certificate of Suitability for ranitidine hydrochloride has been suspended with immediate effect. [EDQM also stated the conditions under which the certificate can be restored]. Saraca is one of GSK's API suppliers. The communication also indicated that the currently agreed threshold in Europe for NDMA in ranitidine hydrochloride is 0.16ppm, and subject to change.
- Based on the information provided above and as a precautionary action, GSK has made the decision to initiate a recall of Zantac products manufactured using API sourced from Saraca Laboratories Limited and Dr Reddy's Limited. The recall is effective 30 September 2019.
- GSK has been responding to the queries received from the Regulatory Authorities and continuing to work actively with them to address their concerns.
- GSK is continuing with investigations into the potential source of the NDMA. These investigations include continued engagement with the API suppliers.
- Patient safety remains our absolute priority.

Actions required:

To support this recall, we would ask that you:

- Examine your inventory immediately and place all the products referenced above under quarantine.
- Check the batch number carefully.
- Immediately return all the affected product batches to your supply wholesaler/distributor for full credit.

We apologise for any inconvenience that this product removal may create and appreciate your cooperation with our request. We appreciate your attention to this important notice and assure you that we are working to resolve and prevent such problems from occurring in the future.

Thank you in advance for your cooperation. If you require additional information regarding this matter, please contact **Aspen Customer Careline** on **0800122912**.

Yours faithfully
GlaxoSmithKline South Africa (Pty) Limited

p.p.

Ms Monica Drögemöller
Responsible Pharmacist

NOTE: Kindly retain this letter in a prominent position for one month, in case there is still stock in transit and inform your customers if possible.