



25<sup>th</sup> September 2019

To,

**BSE LIMITED**  
Phiroze Jeejeebhoy Towers  
Dalal Street  
Mumbai - 400001

**THE NATIONAL STOCK EXCHANGE OF INDIA LIMITED**  
Exchange Plaza, 5<sup>th</sup> Floor, Plot No. C/1, G Block  
Bandra-Kurla Complex, Bandra (East)  
Mumbai - 400051

GlaxoSmithKline Pharmaceuticals Ltd.  
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Mumbai - 400 030

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Dear Sir,

**Sub: Update on the Company's Ranitidine Product**

Pursuant to clause 30, of the Listing Obligations and Disclosure requirements (LODR), Regulations, 2015, We wish to inform you that ;

The Company has been contacted by regulatory authorities regarding the detection of genotoxic nitrosamine NDMA in ranitidine products. Based on the information received and correspondence with regulatory authorities, GSK made the decision to suspend the release, distribution and supply of all dose forms of ranitidine hydrochloride products to all markets, including India, as a precautionary action pending the outcome of ongoing tests and investigations.

Subsequently, Saraca Laboratories Limited were notified by the European Directorate for V Quality of Medicines that its certificate of suitability for ranitidine hydrochloride has been suspended. The Company manufactures Ranitidine Hydrochloride IP Tablets 150 mg and 300 mg (Zinetac) using API from Saraca Laboratories Limited and another supplier, SMS Lifesciences India Limited, for supply to Indian market.

Based on the information provided above and as a precautionary action, the Company has made the decision to initiate a voluntary recall (pharmacy/retail level recall) of Zinetac Tablets 150 mg and 300 mg products manufactured in India using API sourced from Saraca Laboratories Limited. The product manufactured using API from SMS Lifesciences India Limited will not be recalled at this point of time. However, all such products will remain on hold and they will not be released to the market while the Company will await the test results.

GSK is continuing with investigations into the potential source of the NDMA. These investigations include continued engagement with our API suppliers. Patient safety remains the Company's utmost priority and we are taking this issue very seriously.

Kindly take submission on record.

Yours faithfully  
For **GlaxoSmithKline Pharmaceuticals Limited**

Ajay Nadkarni  
Vice President – Administration, Real Estate  
& Company Secretary