SMS Lifesciences India Limited
Registered & Corporate Office :
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Opp. Bharatiya Vidya Bhavan Public School,
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CIN : L74930TG2006PLC050223
Email : info@smslife.in, Website : www.smslife.in

April 9, 2020

To,

BSE Limited.
Listing Department, P J Towers,
Dalal Street,
Mumbai – 400 001.
Scrip code: 540679

Through: BSE Listing Center

National Stock Exchange of India Limited
Listing Department, "Exchange Plaza",
Bandra-Kurla Complex, Bandra (E),
Mumbai - 400 051
Scrip code: SMSLIFE

Through: NEAPS

SUB: UPDATE ON RANITIDINE HCL.

Dear Sir/Madam,

In continuation to our earlier communication dated November 4, 2019, please find enclosed update on the status of Ranitidine HCL.

This is for your information.

Yours Truly,
For SMS Lifesciences India Limited

Sd/-
Trupti Ranjan Mohanty
Company Secretary

Encl: A/a

[This information is being submitted under SD/- mode due to limited resources available, as the Company and its executives are following "Work from home"]

UPDATE ON RANITIDINE HCL.

Ranitidine HCL occupies major contribution in aspect of both volumes as well as value for the company. The said molecule is being manufactured since inception i.e. 1990 and being sold to various markets except highly regulated markets like USA.

We are one of the pioneers in manufacturing and exporting Ranitidine HCL. However, in a discovery in September, 2019 released by one of the scientific laboratory in the US stating that Ranitidine HCL may contain NDMA (N-Nitrosodimethylamine) impurity at low level, which leads to carcinogenic effect on prolonged use of the dosage form.

USFDA on September 13, 2019 informed that they are evaluating the presence of this impurity and the impact (if any) of the same on patients. However, in a fresh news release dated April 1, 2020, USFDA has advised all manufacturers to withdraw all Rx and OTC Ranitidine drugs from the US market immediately as the impurities in some ranitidine products increases over time, when stored at higher than room temperatures and may result in consumer exposure to unacceptable levels of impurity.

USFDA has made an official announcement as reproduced hereunder:

"We didn't observe unacceptable levels of NDMA in many of the samples that we tested. However, since we don't know how or for how long the product might have been stored, we decided that it should not be available to consumers and patients unless its quality can be assured".

The company does not have any Ranitidine API sales to US market either directly or indirectly. We are confident of providing a safe product with continuous improvement as per requirements and shall communicate accordingly with various stake holders. However we need to wait for the guidance of health authorities of ROW / domestic markets. In view of the above, usage of Ranitidine tablets could reduce and the repercussions of the same along with lockdown due to COVID19 pandemic are difficult to assess at the current stage but could impact the revenues of the Company.

Moving forward, Management is closely monitoring all the directives being issued by the Authorities and shall take all necessary steps.

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