



Pharmaceuticals Limited

Registered & Corporate Office :

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CIN : L24239TG1987PLC008066

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Date: 16th October, 2019

To,
The Manager,
Corporate Filings Department,
BSE Limited,
Phiroze Jeejeebhoy Towers,
Dalal Street,
Mumbai- 400 001

The Manager,
Listing Compliance Department,
National Stock Exchange of India Ltd.
Exchange Plaza, Plot no. C/1, G Block,
Bandra-Kurla Complex, Bandra (E),
Mumbai - 400 051.

Security Code:532815

Symbol: SMSPHARMA

Subject: Pursuant to clause 30, of the Listing Obligation and Disclosure requirement (LODR), Regulations, 2016, We wish to further inform you that:

In addition to our earlier communication dated 16th September, 2019 and update on 30-09-2019 through AGM proceedings,

We would like to inform you that we have carried out an analysis of our Ranitidine product and processes and found that the NDMA impurity trace level, in many cases lower than the levels found in normal environmental contaminant and is found in water and foods including meat, dairy products and vegetables. However, we are continuously investigating the root cause at our R&D and Plant level and we are confident that we can establish the process and controls the impurity in the Ranitidine product manufacturing at our facility.

The Company has already submitted the requisite information to European Directorate for the Quality of Medicines (EDQM) and Central Drugs Standard Control Organization (CDSCO). We are continually submitting the information sought by United States Food and Drug Administration (USFDA).

We have submitted the requested Analysis reports to EDQM, as per our testing reports the content of NDMA are within the TTC level of not more than 2.5ppm as per ICH M7 guidance document. However, the EDQM set a new threshold level of not more than 0.16 ppm. According to the new threshold limit of not more than 0.16 ppm set by EDQM, 70% of our product Ranitidine sample complies. Based on the new set level the EDQM temporarily suspended Certificate of Suitability. We are preparing at our end to submit the further requirement of data sought by the Authorities.

We are awaiting feedback/information from USFDA against the DMF updated information and expected to get the same by next couple of weeks.

We further inform you that till date we have not sold any quantities of Ranitidine API product to Europe. However, the quantities sold to our Indian customers for their Europe /US markets but the product has not entered into commercials.

The share of revenue contributed from Ranitidine product during the last financial year 2018-19 @ 0.62% of the total revenues. Hence, there is no material impact on the company's current and future revenues.

We anticipate business as usual in future as we are much confident of providing a safe and stable Ranitidine product to all our customers, well within acceptable limits set by the Drug regulatory authorities.

We shall update you on any regulatory news/findings that can have a material impact on our business in the long term.

Please take the same on your records.

Thanking you

Yours Faithfully

For SMS Pharmaceuticals Limited



V.S.Venkatish
Company Secretary