

September 30, 2020

BSE Limited  
Phiroze Jeejeebhoy Towers,  
Dalal Street, Mumbai – 400 001

**Reg.: Clarification / Confirmation on news item appearing in “Media / Publication”**

**Ref.: Letter No. L/SURV/ONL/RV/NK/ (2020-2021)/ 23 dated September 30, 2020**

Dear Sir/Madam,

With reference to your above referred letter in the captioned matter, we would like to submit as under:

1. The Company has received on September 25, 2020 a Warning Letter dated September 24, 2020 issued by the USFDA relating to pharmaceutical formulation facility at Baddi, Himachal Pradesh, owned by the Company’s unlisted wholly-owned subsidiary, Panacea Biotec Pharma Limited (“PBPL”).
2. The Company / PBPL has taken multiple steps after the inspection of the facility conducted during February 10 to 20, 2020 to address the observations received from USFDA during the inspection. The Company / PBPL will actively engage with the agency and take all necessary steps required to address USFDA concerns. The Company / PBPL is also in the process of providing a thorough and comprehensive response to the USFDA within the statutory time permitted in the letter.
3. This warning letter does not materially affect the existing business of the Company / PBPL in the US and the existing product supplies from the said pharmaceutical formulations facility will continue. Further, US revenues from the said facility is not significant as compared to total revenues of the Company and PBPL. The USFDA may, however, withhold approval of any new drug applications or supplements till PBPL addresses all issues raised by the agency.
4. We are committed to patient safety, quality and take all quality and compliance matters seriously and stand by our commitment to fully comply with the cGMP quality standards.
5. In view of the above, the Company believes that this has no material impact on the business of the Company / PBPL and therefore, it was not disclosed to the Stock Exchanges earlier.

You are requested to take the same on records.

Thanking you,

Sincerely yours,

for **Panacea Biotec Ltd.**

  
**Vinod Goel**  
Group CFO and Head Legal & Company Secretary



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**Panacea Biotec Ltd.**

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