



Biocon Limited

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No: 2017/SEC/JULY/067

JULY 09, 2017

National Stock Exchange of India Limited
"Exchange Plaza", 5th Floor,
Plot No. C/1, G Block,
Bandra-Kurla Complex
Bandra (East), Mumbai – 400051

BSE Limited
Phiroze Jeejeebhoy Towers,
Dalal Street, Fort,
Mumbai – 400001

NSE - Symbol - BIOCON

BSE - Scrip code - 532523

Dear Sir/Madam,

Sub: Company's statement on the outcome of pre-approval inspection audits by French health agency, L'Agence nationale de sécurité du médicament et des produits de santé (ANSM) on behalf of European Medicines Agency (EMA)

Please find below the Company's statement on the subject matter.

"The French inspecting authority (ANSM) conducted pre-approval inspection audits of our Bangalore drug substance and drug product sites related to the pending EMA Marketing Authorization Applications for Trastuzumab, Pegfilgrastim and related to Insulin Glargine (pen assembly only).

While there were no critical observations mentioned in the final report, ANSM notified Biocon that the receipt of a GMP compliance certificate for the drug product facility will require a follow up inspection from ANSM to verify implementation of the proposed corrective and preventive actions (CAPAs). ANSM has reviewed the proposed CAPA plan and Biocon is progressing towards completion of the implementation of these CAPAs. Biocon, with its partner Mylan, will work with the French and European regulatory authorities with regard to the follow-up inspection of the drug product facility and the Marketing Authorization Applications with the goal of an early re-inspection.

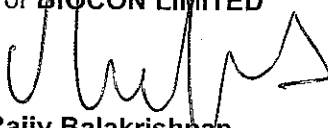
We are pleased however that ANSM has issued GMP compliance certificates for our two drug substance manufacturing facilities in Bangalore. This is important as the drug substance manufacture is core to the production of the actual biologic product in GMP compliance.

Biocon is committed to ensuring the highest level of quality in all of its products." - Company Spokesperson

Kindly take on record the same.

Thanking You,

Yours faithfully,
For **BIOCON LIMITED**


Rajiv Balakrishnan
Company Secretary

