

**Biocon Limited** 

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CIN: L24234KA1978PLC003417

www.biocon.com

No: 2017/SEC/AUG/098

August 16, 2017

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

NSE - Symbol - BIOCON

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

BSE - Scrip code - 532523

**BSE Limited** 

Dear Sir,

Sub: Company Statement on Status of EMA Dossiers.

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

 As previously communicated, whilst our drug substance facilities for Trastuzumab and Pegfilgrastim were approved, the European regulatory authorities had informed us of the need for a re-inspection of our drug product facility for these products.

 The request for withdrawal of the dossiers and re-submission is part of the EMA procedural requirements linked to this re-inspection and will be considered by the EMA's Committee for Medicinal Products for Human Use (CHMP).

• We are on track to complete our corrective and preventive actions (CAPAs) by the end of this quarter and it is our intent to seek re-inspection and re-submission thereafter.

-Company Spokesperson

Kindly take on record the same.

Thanking You,

Yours faithfully,

For BIOCON LIMITED

Rajiv Balakrishnah Company Secretary