



No: 2017/SEC/AUG/098

August 16, 2017

National Stock Exchange of India Limited  
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NSE - Symbol - BIOCON

BSE - Scrip code - 532523

Dear Sir,

**Sub: Company Statement on Status of EMA Dossiers.**

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

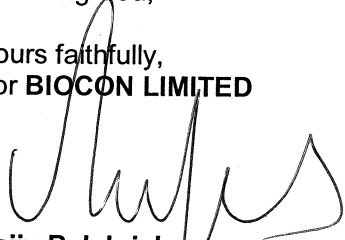
- As previously communicated, whilst our drug substance facilities for Trastuzumab and Pegfilgrastim were approved, the European regulatory authorities had informed us of the need for a re-inspection of our drug product facility for these products.
- The request for withdrawal of the dossiers and re-submission 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 Balakrishnan**  
Company Secretary

