ALKEM

ALKEM LABORATORIES LTD.

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CIN no.:- U00305MH1973PLC174201

ALKEM VISION

To achieve value driven leadership in Indian Health Care Industry and beyond...
Through
Quality that is infinite
Service that cares
Hardwork that endures

16 April 2016

The Corporate Relationship Department **BSE Limited** Phiroze Jeejeebhoy Towers Dalal Street Mumbai 400 001 ***Scrip Code: 539523***	**National Stock Exchange of India Limited** Exchange Plaza Bandra Kurla Complex Bandra East Mumbai 400 051 ***Scrip Symbol ALKEM***

Dear Sir/Madam,

This is with respect to the recent news reports in the media in connection with "Notification to the CHMP/EMA Secretariat of a Referral under Article 31 of Directive 2001/83/EC" (the "**Directive**") made by The Federal Institute of Drug and Medical Devices (BfArM) Germany. For the benefit of all the stakeholders, we would like to provide clarity on the issue as follows:

- The Federal Institute of Drug and Medical Devices (BfArM), Germany, and the Health Care Inspectorate (IGZ), Ministry of Health of the Netherlands performed a joint inspection in March 2015 at Alkem's Bioequivalence facility at Taloja.

- The referral under Article 31 of the Directive refers to bioequivalence studies conducted for the period between March 2013 and March 2015 and in particular to bioequivalence trials of two products, of which one is commercialized and another is yet to be commercialized. We will be submitting a suitable clarifications to the European Medicines Agency ("EMA") within the stipulated timelines to enable the Committee for Medicinal Products for Human Use ("CHMP") take a balanced risk-benefit view with respect to these two products.

- Currently sales from Europe contributes less than 1% to Alkem's total consolidated sales for 9MFY16.

- Further, our Company takes quality issues very seriously and is committed to comply with all the required regulatory norms to ensure that safe and effective products are supplied to the market. After the inspection of March 2015 by German regulator, BfArM, Alkem has responded to the regulator with a robust remedial plan and has also been implementing several measures which include changes in staffing, upgrading equipment and improving quality assurance systems to ensure proper controls during bioequivalence studies and thorough review of the acquired data.

We would request you to take note of the above.

Sincerely,

For **Alkem Laboratories Limited**

Manish Narang
Sr. V.P. Legal, Company Secretary & Compliance Officer