



ALKEM

ALKEM LABORATORIES LTD.

Regd. Office : " ALKEM HOUSE", Senapati Bapat Marg,
Lower Parel, MUMBAI 400 013. Phone : 3982 9999, Fax : 022-2495 2955
Email : contact@alkem.com Website : www.alkemlabs.com
CIN no :- U00305MH1973PLC174201



25th June, 2016

The Corporate Relationship Department BSE Limited Phiroze Jeejeebhoy Towers Dalal Street Mumbai 400 001 <i>Scrip Code: 539523</i>	National Stock Exchange of India Limited Exchange Plaza Bandra Kurla Complex Bandra East Mumbai 400 051 <i>Scrip Symbol ALKEM</i>
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Dear Sir/Madam,

Sub: Update on Article appearing on the website of European Medicines Agency (EMA)

This is in furtherance to our intimation dated 16th April, 2016 and with reference to the recent article appearing on the website of European Medicines Agency (EMA) on studies conducted by the Company at its Bioequivalence Facility at Talaja. For the benefit of all the stakeholders, we would like to provide clarity on the issue as follows:

The Committee for Medicinal Products for Human Use (CHMP) of EMA has given the following specific recommendations:

- *"Cefuroxime Alkem and Cefuroxime Krka (antibiotics) can remain on the market in the EU, as alternative studies have been provided that support a positive benefit-risk balance."*
- *"Cefuroxime Ingen Pharma, currently under evaluation by national authorities, can still be considered for authorisation, as studies from other sources have been provided by the Company."*
- *"Ibuprofen Orion, a painkiller currently under evaluation by national authorities, cannot be authorised on the basis of studies carried out at Company. So far no alternative studies from other sources have been provided." **The Company is considering to provide the alternate studies from other sources to support authorization.***
- *"Riluzole Alkem, a medicine for amyotrophic lateral sclerosis (ALS) which is yet to be marketed in the European Union (EU), should be suspended." **The Company is considering to provide the alternate studies from other sources to support authorization.***

We would like to inform you that it has been clearly stated in the aforesaid Article that there is no evidence of harm or lack of effectiveness with any of the medicines linked to studies conducted by the Company and that the patients should continue to take Company's medicines as prescribed.



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Currently sales from Europe contributes less than 1% to Company's total consolidated sales during FY 2015-2016.

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.

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