



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



9th 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 Sirs

Sub: Clarification on News Report captioned "Drug Regulator finds Alkem Labs drug substandard, again" appearing in Business Standard edition published on 9th June, 2016

This is with reference to the clarification sought by Exchanges in connection with the news report captioned as above.

In this regard, we are enclosing herewith the clarification statement, the contents of which are self explanatory.

Kindly take the same on record.

Sincerely,
For Alkem Laboratories Limited

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



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Clarification on News Report captioned "Drug Regulator finds Alkem Labs drug substandard, again" appearing in Business Standard edition published on 9th June, 2016

Alkem Laboratories Limited ("Company") manufactures and markets anti-diabetic drug under the brand name "Glimikem". In the month of June and July 2015, the Central Drugs Standard Control Organisation ("CDSCO") issued alerts against two batches of the said product on account of the products in the identified batches not meeting the I.P. specification with respect to dissolution and accordingly, the Company had recalled specific batches from the market.

Subsequently, the Company improvised the formulation of Glimikem and started manufacturing this formulation from the month of February 2016.

The two additional batches shown on CDSCO website and notified by the Agency are from the earlier formulation of Glimikem product that was in the market prior to the release of the improvised formulation of Glimikem batch manufactured in February 2016.

The issues highlighted by CDSCO regarding the products in the identified batches not meeting the I.P. specification with respect to dissolution had no impact on the safety and efficacy of the product, however, the Company is in process of voluntarily recalling the remaining batches of Glimikem manufactured prior to February 2016. The batches manufactured from and after February 2016 shall continue to be available in the market.

Further, sale of Glimikem is negligible as compared to the total turnover of the Company. Glimikem contributed less than 0.001% of the total turnover of the Company as on 31st March, 2016.

The product is not a material product and receipt of the notice in relation to the specific batches and their recall would not have impacted the performance and financial position of the Company significantly. The same was to be disclosed to the Exchanges if the event could be categorised as a material event as per Regulation 30 (3) and Regulation 30(4) of the SEBI (Listing Obligations and Disclosure Requirements) Regulations, 2015. As per the policy for determination of materiality approved by the Board of Directors all events / information would be considered material if its financial impact on the Company is 5% or more of the gross turnover as per the last audited consolidated accounts of the Company.

In view of the above, we believe the receipt of the notice does not amount to be a material event and hence no disclosure regarding the same was made to the Exchanges under Regulation 30 of the SEBI (Listing Obligations and Disclosure Requirements) Regulations, 2015.

Message to Doctors and Patients:

Alkem Laboratories Limited is an ethical and patient centric Company and we assure the Doctors and Patients that Glimikem continues to be as safe and effective drug and trusted brand as before.