

Date : 9th May 2018

To :

The Management of Cipla

Y.K.Hamied – Chairman

Samina Vaziralli – Executive Vice Chairman

M.K.Hamied – Vice Chairman

Umang Vohra – Managing Director & Global CEO

S Radhakrishnan – Whole Time Director

Peter Mugyenvi - Independent Director

Punita Lal – Independent Director

Ireena Vittal – Independent Director

Ashok Sinha – Independent Director

Adil Zainulbhai – Independent Director

Naina Lal Kidwai – Independent Director

Peter Lankau – Independent Director

Subject : Death of my wife from Serious Adverse Drug Reactions of IV Rokfos.

Enclosed, please find the following :

- a) My letter to Ms Jyoti Sardesai, Director - Food and Drug Administration, Goa.
- b) My letter to Dr.Avinash Kakade (Head – Global Pharmacovigilance, Cipla) demanding apology from him as well as CIPLA MD and Gobal CEO Umang Vohra for false, baseless and defamatory information on my wife's health. This after Cipla drug was the cause of her death.

BRIEF FACTS OF THE CASE

1. My wife Smt.Kamini Barkur was admitted to Maruti Nursing Home, Mulund, Mumbai for Cervical Spondylitis and Stiff Neck. Cervical spondylitis was diagnosed prior to admission to the nursing home and cause of stiff neck had to be diagnosed by MRI and accordingly MRI was the first line of action as per in-patient records of my wife.
2. Instead of MRI, she was administered IV Rokfos for no reason mentioned in in-patient records of my wife.
3. Rokfos caused serious adverse drug reactions never seen before as per the treating doctors at Maruti Nursing Home. However, they suppressed the ADRs in their in-patient records as well as in the case filed by me before the Maharashtra State Consumer Disputes Redressal Commission. On the other

hand they have submitted to the Maharashtra Medical Council that the drug did not suit my wife and hence he discontinued it.

4. These ADRs were reported by the doctors to Cipla medical representative as well as the medical advisor.
 5. I had myself informed Cipla Drugs Safety Division within seven weeks of death of my wife to investigate in the interest of medical science and for me to take action against the treating doctors. I had given batch no. manufacturing date and expiry date. There was plenty of stock left with the company as the manufacturing date was just six months ago. There were five injections in the invoice produced by the doctors. The remaining four injections were withdrawn by them.
 6. This batch was manufactured at Goa plant against which there have been several complaints, warnings and observations by US FDA.
 7. Obviously, failure to follow Schedule M of Drugs and Cosmetics Rules was due to the drug being sub-standard.
 8. Besides, administering this drug to cure stiff neck in a single day was a clinical trial conducted by the doctors at the behest of Cipla Ltd.
 9. It was the office of the DCGI who gave me the information that Cipla had to recall this drug Rokfos for testing the batch for quality. They have asked FDA, Maharashtra to investigate and take action.
 10. I have filed a case with the Police through PMO Public Grievance. Since explanation has been received now from Cipla wherein they have admitted to ignorance of the Laws as well as false evidence given by Dr. Avinash Kakade to the Director of FDA, Goa, it is obvious that Cipla will be penalised by the Drug Control Authorities CDSCO, FDA, Ministry of Health, etc.
 11. Also Cipla is liable for culpable homicide causing death of my wife by sub-standard drug Rokfos administered as a clinical trial.
 12. Cipla should not play with the lives of the citizens of the country. Their lives are also valuable and cannot be used as GUINEA PIGS for experimentation and clinical trials.
 13. Finally, I expect an unconditional apology from the management of Cipla for defamatory and false information on the health condition of my wife prior to drug IV Rokfos being given without any evidence.
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14. Paralytic Arm ? The doctors at all three hospitals where my wife was admitted and later shifted after bone marrow failure must have been blind not to notice a paralytic arm ?
15. My wife does not deserve this as she was hale and hearty prior to being administered Rokfos. Her life was destroyed within a day (less than 20 hours) of being administered this injection.
16. I expect a quick and unconditional apology from Cipla as it is more than three years that I have been seeking justice. I have been expecting answers from Cipla for four years. They have broken their silence when the government authorities have issued a Show Cause Notice.

Umeshchandra Barkur
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