

01-05-2018

Dr.Avinash R Kakade

Head Global Pharmacovigilance - Cipla Ltd

Subject : Adverse Drug Reaction of ROKFOS – Explanation to notice received.

Please refer to Page 2 of 3 of Additional Information.

You have stated “The patient’s concurrent conditions included spinal tuberculosis, cervical spondylitis, arthralgia and one paralytic arm”. “On an unknown date the patient received one shot of steroid for tuberculosis treatment“

Where did you get these information from ? Can you produce the evidence ?

My wife had come walking to Maruti Nursing Home as she was hale and hearty except for the stiff neck.

For your information, as per MRI report – Findings were suggestive of infective etiology like Koch’s. Clinical correlation and follow-up were suggested. Clinical correlation and follow-up was not done by Dr.Mihirgiri Goswami as a bigger disaster from Cipla drug IV Rokfos occurred.

Do you have proof of spinal tuberculosis ? Do you have proof of paralytic arm ? Do you have proof of one shot of steroid for tuberculosis treatment ? The treating doctor has noted in in-patient records of my wife “Post Zobone Arthralgia” meaning joint pains after injection Zoledronic Acid.

It was Cipla drug which caused my wife to be in severe bodily pains within 24 hours of the drug being administered and she was bed-ridden till her death. Besides, blood disorders (pancytopenia), petechial rashes, dysphagia, myalgia, bone pain and back pain were all due to side effects of ROKFOS. Cipla Drugs Safety had given this information to me vide their e-mail. Also they had sent your medical representative with the booklet on ROKFOS to Maruti Nursing Home. The treating doctor admitted that such adverse reactions from ROKFOS were never seen before by them. And they were your most valued customer selling ROKFOS to several hospitals and orthopaedics. That too illegally without a valid licence.

These false statements were made by you to none other than Directorate of Food and Drugs Administration, Government of Goa. Also to the Director, Department of Public Grievances, Government of Goa.

You have chosen to malign my wife with concocted stories regarding her health condition to show to the government authorities that my wife was severely ill. Paralytic Arm ? Do you know what you are saying ?

It was Cipla Drug which was administered as a **clinical trial to cure stiff neck** in a single day. You have played with my wife's life as also with the lives of several citizens of this country by not recalling the sub-standard drug ROKFOS. You have admitted to **"IGNORANCE OF LAWS PERTAINING TO DRUGS AND COSMETICS"**.

You have now chosen to defame my wife even after her death due your drug ?. I will file a civil and criminal defamation suit against you and Cipla.

You have to apologise to both the government authorities – FDA, Goa as well as Dept. of Public Grievances, Goa and withdraw your statements immediately.

These false statements and lies clearly prove in no uncertain terms your depraved mental condition. This is proof that Cipla company policies and morals are unethical and Rokfos treatment was as a CLINICAL TRIAL only. Hence the suppression of the serious adverse drug reactions. **That Cipla will not shy away from playing with the lives of the citizens of this country.**

The morals and ethics of CIPLA also agree with those of the doctors at Maruti Nursing Home and hence the NEXUS between the two.

Pharmaceutical experts, pharma activists and consumer activists will see that Cipla Licence is cancelled for their malpractices threatening the lives of the citizens of INDIA as also elsewhere in the world.

Umeshchandra Barkur

A-15, Neeta Apartments, Chaphekar Bandhu Marg,

Mulund East, Mumbai 400081.

Cc: Jyoti J. Sardesai – Director, Food and Drugs Administration,

Government of Goa.

Cc: The Director, Department of Public Grievances, Government of Goa.

Cc: Shri A.M.Khadtare – Joint Commissioner, FDA, Maharashtra.