Date : 14th May 2018

The Joint Commissioner -- FDA, Greater Mumbai Division

Shri A.M.Khadtare

Sir,

Subject : Death of my wife from serious adverse drug reactions of injection IV Rokfos manufactured by Cipla Ltd.

Enclosed, please find my letter to Cipla Management demanding an unconditional apology for false, baseless and defamatory information given to Director - Food and Drug Administration, Goa on the health condition of my wife prior to being administered injection IV Rokfos for curing stiff neck in a single day..

This is again a reminder to you asking for actions taken by FDA, Maharashtra, Mumbai against A. Maruti Nursing Home B. Cipla Ltd. C. FDA, Maharashtra, Mumbai officials.

The actions are requested by A. DCGI B. PMO complaint forwarded by Drugs 2 department, Mantralaya C. Office of Minister for Food, Civil Supplies, Consumer Protection and FDA and D. Office of the Chief Minister of Maharashtra.

Please refer to the detailed facts with evidence sent to you including explanation by Cipla on the serious adverse drug reactions.

1. **Maruti Nursing Home doctors :**

Proof of the serious adverse reactions have been provided by way of :

a) In-patient record noting by treating doctor that the severe bodily pains were after injection zoledronic acid (Rokfos) was administered to my wife.

b) The treating doctor's submissions to Maharashtra Medical Council that the said drug did not suit the complainant's wife and that he had withdrawn it.

c) That he had purchased the drug from a licensed stockist which confirms the serious adverse drug reactions and hence the defence of being purchased from a licensed stockist.

d) That he had administered Rokfos but the nurse has written Zobone inadvertently as both were same medicines of same strength.

e) Transcripts of meeting between doctors and relatives of the deceased clearly proves the nexus between Maruti Nursing Home doctors and Cipla Ltd into sale of sub-standard drug IV Rokfos and also specially manufactured batches given to Dr.Dubey of Maruti Nursing who took the responsibility of the drug and saw that neither the patient was in trouble and nor was the treating doctor. That he had to balance both. That he sold Rokfos to several orthopaedics.

f) That the doctors had never seen such dramatic allergy and adverse reactions from this drug IV Rokfos ever before.

g) This proves why Cipla did not recall their drug mandatorily as per Schedule M of the Drugs and Cosmetics Rules. This even after being informed by me to do so in the interest of medical science.

h) As per the transcripts of the meeting, the treating doctor Dr.Mihirgiri Goswami says that their regular brand was Zobone and Rokfos was their new brand which caused the disaster and that he will not give Rokfos any more. That he gave Rokfos for curing stiff neck in one day "Give today, discharge tomorrow".

i) The above is proof of culpable homicide as "Purchase, Stocking and Sale was illegal". That this drug caused grievous hurt within the meaning of section 320 of the IPC. That instead of saving the life of the patient after the serious adverse drug reactions, the doctors watched my wife sinking to her death. Besides they clandestinely and in a treacherous manner sent her for surgery in a critical condition. This was attempt for culpable homicide since as doctors they knew that patient would bleed to death during surgery as there was hardly any blood left in her body. The doctors had abandoned the patient after six days under their care without any information to the receiving hospital, Platinum Hospitals. Platinum Hospitals have confirmed in their affidavits to the Hon'ble Maharashtra State Commission that it was they who informed me the seriousness of the patient's condition. That my wife needed blood and not surgery. That they immediately shifted my wife to the ICU within an hour after admission to Platinum Hospitals.

j) There is no way that FDA officials could have not arrested Maruti Nursing Home doctors for illegal drugs sold which has taken a precious and innocent life. It was unnatural, untimely and merciless death.

k) Even till this day they are making a mockery of a consumer and openly protecting the killer. They should be made answerable for the inconvenience, trauma and loss caused to the public due to their failure to act on time and to make them liable for such inaction.

2. Cipla explanation and falsehood to the Director of Food and Drug Administration, Goa.

a) My e-mails to Cipla is proof that the serious adverse drug reactions of IV Rokfos were reported to them by the aggrieved party immediately after the death of my wife.

b) Maruti Nursing Home also reported to Cipla medical representative as well as their medical advisor of the serious adverse reactions.

c) Confirmation of the ADRs is due to the fact that Cipla sent their indications of use of Rokfos to the treating doctor to be given to me. Cipla sent me an e-mail that the doctor is the right person to decide whether a drug has to be given or not. Cipla also sent me the indications of use of IV Rokfos.

d) Cipla did not contest the serious adverse reactions at that time as they were aware of their sub-standard drug given as clinical trials. It was a very simple task of taking one sample from Maruti Nursing Home from the remaining four injections and test for quality.

e) Cipla was aware of the faulty manufacturing practices at their Goa Plant reported by warnings and observations by US FDA several times.

f) Cipla has accepted that they have violated Schedule M of the Drugs and Cosmetics Rules. This in spite of being advised by the doctors as well as myself on the serious adverse reactions never seen before. There was plenty of stock left with Cipla and four injections were withdrawn by Maruti Nursing Home. Precious lives were at stake.

g) That in future Cipla will conduct product quality investigations into all death cases resulting from the use of a Cipla drug. Will also submit reports of

serious adverse drug reactions to the concerned licensing authority and also to DCGI and PVPI.

h) Cipla is not above the law of the land. What about death caused ? Who is responsible and who will pay the penalty and bear the punishment as per the laws of the country ?

i) Cipla has broken their silence after four years and are going extra miles to protect their drug Rokfos more than the doctors. The doctors had suppressed the serious adverse drug reactions to the extent of watching the patient sink to her death. They were caught as explained under paragraph 1. above.

j) Cipla has lied and cheated the Director of FDA, Goa on the health condition of my wife prior to administration of Rokfos which destroyed her life in less than a day (20 hours).

k) Cipla has concocted false stories on the health condition of my wife without any evidence. It seems that in their desperate situation of being caught in an act involving Culpable Homicide, they have tried to defend their drug by false concocted stories on the health history of my wife than the several doctors treating her at Maruti Nursing Home, Platinum Hospitals and Jupiter Hospital.

l) As per Cipla's baseless and false explanation, they overlooked the fact that a paralytic arm would have been recorded in the patient's in-patient records. That arthralgia was not on admission to Maruti Nursing Home but after being administered injection zoledronic acid. That spinal tuberculosis would need proof of test reports. That one shot of steroid to treat tuberculosis would need nursing home records.

m) Cipla is defending the doctors that the drug was given for treatment for osteoporosis. My wife was not admitted for osteoporosis. There is no mention of osteoporosis in the in-patient records of my wife and nor have the treating doctors mentioned treatment for osteoporosis in their submissions before the Hon'ble Maharashtra State Consumer Disputes Redressal Commission.

n) There is conclusive proof that Rokfos was given as a CLINICAL TRIAL at the behest of drug maker Cipla Ltd which deserves punishment in line with punishment for serious criminal offences like terrorist activities.

o) The license of Cipla has to be forthwith cancelled.

3. FDA, Maharashtra, Mumbai Complaints :

a) I had informed FDA Joint Commissioner in April 2015 about my wife being administered IV Rokfos at Maruti Nursing Home and being taken in a critical condition after six days ultimately resulting in her death.

b) I had also registered a complaint that drugs were sold above MRP as advised to me by department of metrology to do so with FDA. I had submitted purchase bill for 5 injections of Rokfos as well as Final bill of my wife on her discharge from Maruti Nursing Home.

c) I followed up on this complaint with selective excerpts of the meeting between doctors and relatives of the deceased wherein the doctors had admitted to the serious adverse drug reactions never seen before. The audio CD was given to Mr.J.B.Mantri by me personally.

d) Drugs were sold illegally and case was filed at 15th Court, Mazgaon.

e) Purchase was illegal, stocking was illegal and Sale was also illegal. This drug Rokfos caused serious adverse reactions (Grievous Hurt within the meaning of section 320 of the IPC). There is no defence by the doctors for standard quality of the drug as purchase as well as sale was in itself an illegal act.

f) FDA officials had to arrest the three doctors involved in illegal drugs racket and conducting clinical trials at the risk of lives of the citizens.

g) This action should have been taken long time ago against the following :

- Dr.Mihirgiri Goswami (treating doctor).
- Dr.Meghal Goswami (purchaser of illegal drugs).
- Dr.Dubey (doctor involved in sale of illegal drugs to other hospitals and orthopaedics).

4. Complaint to PMO (PMOPG/E/2018/0109827) & PMOPG/D/2018/0101577.

a) FDA, Mumbai officials are not acting against Maruti Nursing Home doctors as well as the drug manufacturer Cipla Ltd on the serious adverse reactions of their drug.

b) FDA, Mumbai officials are protecting the killers rather than the consumer.

c) My complaint to Joint Commissioner has been manipulated at the Mazgaon Court and serious adverse reactions have not been informed to the Court. Nothing of my complaint is in the drug inspector's submissions to the Mazgaon Court.

d) My complaint has not been recorded at the Mazgaon Court. That it was a complaint from a confidential informer. Joint Commissioner, Maharashtra O.Sadhwani, Assistant Commissioner (Zone 4), Mumbai J.B.Mantri and drug inspector A.T.Rathod have colluded with the doctors of Maruti Nursing Home as well as Cipla Ltd. and this is gross dereliction of duty in line of consumer protection. They have to be booked for acting in collusion or failing to act upon for an act of culpable homicide and suspended from service and investigation ordered for this MAHA FDA SCAM.

e) Eight months later the doctors get a license for selling drugs by the same FDA officials at a different location and drugs are returned to the doctor without a fine being levied.

f) Purchase invoice of Rokfos showed 5 injections.

g) Names, addresses and other details of other patients administered Rokfos had to be produced during drugs seizure. Within 1 year and three months five injections were used. One was given to my wife. The remaining four were withdrawn. As per Indian Medical Council Code of ethics, in-patient records have to be maintained for three years.

h) Drugs were in fact not seized but advised to be stored at temperature less than 25 * C.

i) It is a MAHA FDA SCAM and needs to be investigated by the government in the interest of the residents of Maharashtra.

5. **My complaint to the Honourable Chief Minister of Maharashtra and Food, Civil Supplies, Consumer Protection and FDA Minister :**

a) FDA, Maharashtra, Mumbai officials say that they have no jurisdiction to act against Cipla even after their drug caused serious adverse reactions resulting in death of my wife. The reason given to me is that the drug was manufactured in Goa.

b) Cipla was incorporated in Mumbai in 1935 and its headquarters is in Mumbai.

c) This in effect means that residents of Maharashtra cannot address their grievances with FDA, Maharashtra related to drugs even if the drug has taken an innocent life.

d) Who will the drug manufacturing company outside Maharashtra be accountable to if they sell sub-standard drug causing death of a person within the State of Maharashtra ?

e) Under the circumstances, the government of Maharashtra has to take this issue with the Central government and make new laws for accountability in cases of inter-state sale of drugs.

f) FDA, Mumbai officials have to explain why they cannot accept a complaint on serious adverse drug reactions leading to death and arrest the criminals selling drugs illegally.

6. **Actions required to be taken by FDA, Maharashtra, Mumbai along with CDSCO.**

a) Immediate arrest of all the three doctors mentioned above involved in illegal drugs racket causing untimely and unnatural death of my wife.

b) Immediate action against Cipla personnel involved in sale of sub-standard drug Rokfos given as a clinical trial.

c) Immediate Show Cause Notice to Dr.Avinash Kakade of Cipla for false, baseless and defamatory information on my wife's health condition and stern action against him. A defamation case should be filed against him.

d) CDSCO and FDA should cancel Cipla license, Marketing ban enforced, Confiscation of all products and distributed to government hospitals after testing for quality. Hefty fines and jail terms for persons involved in clinical trials and adequate compensation to the aggrieved party as envisaged in the draft new pharmaceutical policy and proposal by CDSCO for compensation provision in cases of Adverse Drug Reactions.

e) Unconditional apology from Cipla Management for false, baseless and defamatory information of my wife's health condition given to the Director of FDA, Goa. This after their drug was the cause of their death. She was hale and hearty without any history of illness. Her life was destroyed by IV Rokfos from Cipla in less than a day (within 20 hours).

It is three years that I am knocking at the doors of FDA, Maharashtra, Mumbai. I have addressed my grievance due to criminal offences by both Maruti Nursing Home doctors as well as Cipla Ltd.

What will the consumer have to resort to seeking justice for death of his wife if the law enforcement agencies do not act. Rather they are assisting the criminals.

I have addressed my grievance to :

a) Government - Law makers (PMO,CMO and Minister, FDA).

b) Parliament - Laws are in place as advised to me by DCGI. Laws being violated are admitted by Cipla as well as Maruti Nursing Home.

c) Judiciary - The Law enforcement agencies have to take the matter to the Judiciary as per our Constitution. The judiciary will decide on the quantum of punishment.

d) Which Pillar of our Democracy is left for the common man - Media ? Can the Media deliver justice to the consumer or Food and Drug Administration – Maharashtra, Mumbai ?

Hoping for immediate stringent actions against all the accused.

Thanking you for your co-operation,

Yours Sincerely,

Umeshchandra Barkur