

18th April, 2017

The Managing Director & Global CEO
Cipla Ltd,
Cipla House,
Peninsula Business Park,
Ganpatrao Kadam Marg,
Lower Parel,
Mumbai – 400 013.

For the kind Attention of Mr. Umang Vohra

Dear Sir,

**Subject : Death of my wife due to Adverse Drug Reactions of IV Rokfos at
Maruti Nursing Home, Mulund East**

Please refer to my earlier e-mails in respect of the death of my wife due to Adverse Drug Reactions of IV Rokfos, attached viz.

1. My mail dated 26/08/2014 to Dr. Akhtar addressed to prc@cipla.com,
productqueries@cipla.com
2. Dr. Akhtar's reply dated 27/08/2014 from drugsafety@Cipla.com
3. My mail dated 07/07/2016 addressed to drugsafety@Cipla.com
4. Reply dated 07/07/2016 from drugsafety@Cipla.com

At the outset, this mail is only to get information from Cipla on specific points towards the end of my letter in order to follow up on my cases filed at Maharashtra State Consumer Disputes Redressal Commission and with Food and Drugs Administration. I am only interested in knowing what action Cipla has taken after ADRs were informed to Cipla, CDSCO, National Pharmacovigilance Centre at New Delhi and BYL Nair Hospital, Mumbai and also to Food and Drugs Administration (FDA) by me.

Dr. Goswami has admitted that he has informed Cipla Medical Advisor regarding the death due to IV Rokfos.

I am giving brief facts of the case below:

- The adverse reactions occurred at Maruti Nursing Home, Mulund East on 10th June 2014 and discussed with your Medical Advisor, Dr.Akhtar subsequently by me via phone and vide e-mail.
- On 9th June 2014, my wife had come walking to Maruti Nursing Home with a complaint of Stiff Neck and Cervical Spondylitis. X-ray (only of cervical spine) said "mild osteoporosis seen".
- IV Rokfos was administered by Dr.Goswami at 8.00 p.m. without patient's consent, without bone density tests or MRI Scan and without conducting the most crucial "Creatinine Clearance Test" (Refer Cipla indications of use).
- On 10th June, she was sent for MRI Scan and she went by auto from Mulund East to Mulund West. MRI showed cord compression and surgery was fixed for 16th June at Platinum Hospitals.
- At around 5 p.m. (on 10th) i.e. within 24 hours of IV Rokfos being administered, she started complaining of severe arthralgia, myalgia, bone pain and back pain.
- On 11th, she had dysphagia (difficulty in swallowing)
- and on 11th itself, petechial rashes appeared on her arms and legs.
- On 12th, she was in pancytopenia. WBC fell from 20,080 to 2,300 in a single day and platelets fell from 143,000 to 95,000.
- On 13th, platelets fell again from 95,000 to 59,000.
- Petechiae and Pancytopenia are characteristic features of Aplastic Anemia or Bone Marrow Failure. No action by Dr.Goswami since 12th June evening till 14th June. My wife died of Aplastic Anemia.
- On 14th, she was shifted abruptly, in a panic, on a stretcher (She could not get up till her death – which means "Grievous Hurt" as per Drugs

and Cosmetics Act, 1940) without any details of treatment, diagnosis, tests conducted and condition of the patient, except "Shift to Platinum for Surgery".

- Platinum Hospitals admitted the patient and conducted necessary tests for surgical fitness. Within one hour she was declared critical and shifted to ICU. Thereafter she was shifted to Jupiter Hospital and later succumbed to her death on 24th June 2014.

I started investigation into the death of my wife by following up with the doctors involved in her treatment. A meeting was arranged by Dr.Goswami on 22nd August 2014 with relatives of the deceased.

Cipla had sent Indications of use of Rokfos to Maruti Nursing Home which was given to me before the meeting.

All the adverse side effects as occurred in the case of my wife are explained in the indications of use sent by Cipla.

- A sting operation was conducted by NDTV on Delhi doctors called "Bribes for Prescription" on 11th August 2014 and is available on the internet (copy attached).
- The Health Minister had taken up the matter in the Parliament the next day and Ethics Panel of MCI had assured that action will be taken against the doctors for **prescribing unnecessary and costly drugs** just for incentives with scant regard to the effects on the patient's health.
- Taking cue from this, I recorded the meeting in my mobile memory card.

Selected extracts as far as Cipla and Rokfos are concerned are as follows:

On being questioned as to what action he took after ADRs, Dr.Goswami's replies are as follows:

- "I have told that company fellow who comes to meet us. That's why he came up with this article"

- “Abhi, I am also afraid to give Rokfos”
- “We have to send it as a report to the company which they call ADR and they have to take steps”
- “And this is definitely one rare reaction with zoledronic acid. We are also shocked”
- “I am saying you how these companies ultimately get these reports adverse reaction ka. Ultimately they put a ban on this thing.”
- “Cipla has reported as adverse reaction”
- “I have reported to their person, the medical advisor”

Further, upon my complaint that my wife was shifted in a critical condition after six days and she later passed away, as also drugs sold above MRP (Rokfos sold at rupees 3,500) the Drug Inspector raided the premises of Maruti Nursing Home and confiscated drugs worth five lacs and eight thousand. They did not have a valid licence as per Drugs and Cosmetics Act,1940.

A case has been registered at Addl.Chief Metropolitan Magistrate, Mazgaon. Mumbai under section 18 (c) punishable with minimum three years imprisonment which can extend upto three years. Also fine three times the drugs confiscated which in this case is rupees fifteen lacs and twenty-four thousand.

My case at the Hon Maharashtra State Consumer Disputes Redressal Commission has reached the FINAL HEARING STAGE. This case is for “Deficiency in Services” and “Medical Negligence”.

Illegal sale of drugs is the grossest deficiency in service. No action on drug Rokfos causing ADRs one by one for five days and finally sending the patient for surgery should be gross medical negligence.

My concern is **Justice for my wife's death due to illegal sale of drugs** and the same drugs causing "**Grievous Hurt**" within the meaning of section 320 of the Indian Penal Code, ultimately leading to her death.

FDA officials have told me "Purchase was illegal and Sale was illegal". There cannot be justification for the authenticity of the drugs being standard quality.

The punishment in this case is minimum ten years imprisonment which may extend upto Life. Fine minimum rupees ten lacs or three times the value of drugs seized. In this case rupees fifteen lacs and twenty-four thousand.

The stock of drugs seized on a single day is valued at rupees five lacs and eight thousand. **Imagine the thousands of patients being fed with unnecessary drugs and the effect it must have had on their health.**

Several drugs were administered to my wife even before diagnosis and blood samples taken. Bill also says "Other In-house medicines – rupees 1,000/-" **It was blatant abuse of drugs sales just for Profit.**

In this case it led to death and hence Dr.Goswami and Maruti Nursing doctors are caught for their crimes against patients.

and rightly as per the law, it deserves Life imprisonment.

I am seeking answers to the following points from CIPLA:

- I am not accusing Cipla in any manner.
- Although Cipla has replied to my mail and has expressed regret for the death of my wife, there is no report by them to FDA about their drug causing ADRs. They have sent the indications of use to Dr.Goswami as well as the Complainant.

- What is the reason that CIPLA did not investigate into their drug Rokfos causing severe Adverse Reactions ultimately leading to the patient's death ?
- Why did CIPLA not inform FDA or CDSCO about these rare disorders ultimately leading to death ?
- Was it because of bad publicity or to protect Dr.Goswami who failed to take action as the drugs were sold illegally ?
- Or was the drug really sub-standard ?
- There is no information forthcoming from CIPLA, FDA, Maruti Nursing Home as also other hospitals involved in the treatment.

I need to put my complaint before the Prime Minister's Office and Central and State Health Ministers.

I will seek the PMO's help in asking FDA to intervene in my complaints to them so that justice is meted out to me as per Law.

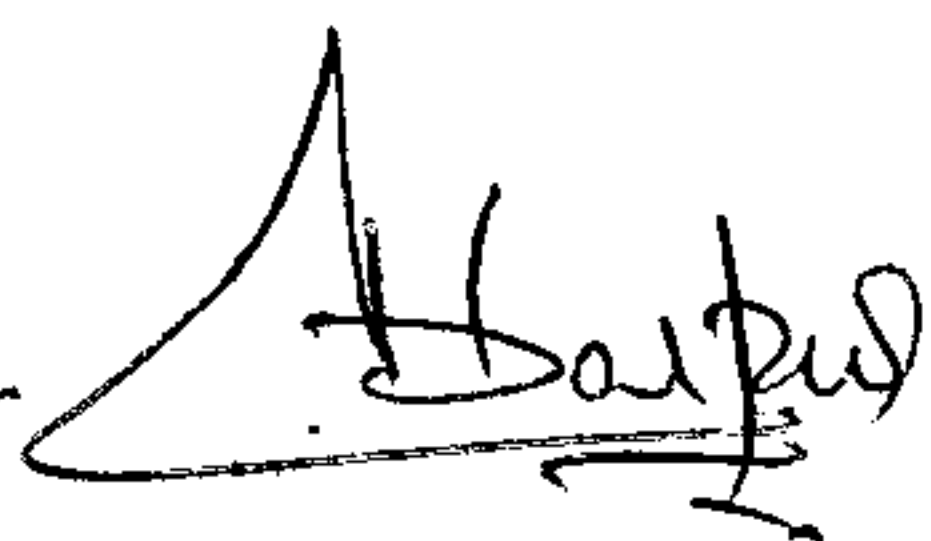
If you can give me your valuable input to help me seek justice, I can include the same in my complaint to the PMO.

Hoping for an early reply,

Thanking you for your co-operation,

Yours Sincerely,

Umeshchandra Barkur



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