Date : 6th June 2018

To :

Cipla Management

Re: Letter from Authorised Representative of Cipla Limited (name unknown) dated 31 May 2018 (Enclosed).

1. Cipla Limited is criminally liable for culpable homicide due to their sub-standard drug IV Rokfos causing serious adverse reactions resulting in death of my wife late Smt. Kamini Barkur.

   a) The serious adverse drug reactions that started within 20 hours of Rokfos being administered were as follows :

      - Arthralgia (joint pains), Myalgia (muscle pain), bone pain and back pain.
      - Dysphagia (difficulty in swallowing).
      - Petechial rashes (bleeding from under the skin).
      - Pancytopenia (drop in all three blood counts). WBC fell from 20,080 to 2,300 and platelets fell from 143,000 to 95,000 in a single day.
      - All the above mentioned ADRs are in the indications of use of drug IV Rokfos sent to me by Cipla Limited **(Refer pages 31-45).**

   b) Petechial rashes and pancytopenia are typical symptoms and characteristic features of Aplastic Anaemia or Bone Marrow Failure as per medical textbooks on Aplastic Anaemia. Aplastic Anaemia was the cause of my wife's death. Bone Marrow Failure occurred at Maruti Nursing Home itself.

   c) My wife had come walking to Maruti Nursing Home as she was hale and hearty except for the stiff neck. She had no history of any illness. Her life was destroyed in less than a day (within 20 hours) by Cipla drug Rokfos.

   d) **Under Para 14, clause f, page 4 of Cipla letter dated 31 May 2018,** they say that the company had immediately **informed the appropriate licensing authority of the adverse event.** This is a **false statement**. Refer letter from FDA, Goa dated 17/01/2018 addressed to me **(Page 46).** They have stated that FDA, Goa has not received any report of serious adverse drug reactions

of IV Rokfos from Cipla Ltd. That handling of product complaint and complaint related to ADR are investigated by Drug Safety Department, Cipla, Mumbai and not at Cipla, Goa location. FDA, Mumbai has not received any report from Cipla. I have been following with them since several months.

Further, under the same paragraph, Cipla authorised representative says that the explanations given to FDA, Goa on non-compliance of Schedule 'M' has no relevance to the issue at hand.

Non-compliance of Schedule 'M' is the most crucial evidence that drug IV Rokfos was sub-standard. These were specially manufactured batches for Maruti Nursing Home to treat stiff neck, joint pains, bone pain and other minor bone problems. Cipla admitting violation of the laws relating to drugs and cosmetics to Director of Food and Drugs Administration, Goa citing ignorance of Schedule 'M' is shocking. Coming from an International pharmaceutical giant, this is unbelievable and unpardonable. It is none other than the office of Drugs Controller General of India who had given this information to me **(Refer page 47-48).** Cipla cannot override and ignore the highest Central Government authority, DCGI who have asked concerned authorities to examine the matter and to take necessary action.

Maruti Nursing Home doctors did not take any action on the serious adverse drug reactions for five days and later abandoned the patient under their care for six days. This could be compared to committing a murder and then absconding. The receiving hospitals, Platinum Hospitals and Jupiter Hospital also suppressed the ADRs in their in-patient records. As per treating doctor, Dr.Mihirgiri Goswami, he had discussed drug Rokfos with Pharmacologist, Dr.Rathod at Platinum Hospitals and also with haematologist treating my wife at Jupiter Hospital. This was conveyed to me in an e-mail dated 1st August 2014 **(Refer page 50).**

As per Cipla, they were informed by Dr.Mihirgiri Goswami of the ADRs on 7th August 2014. I had informed Cipla of the ADRs on 16th August 2014. Further I had again informed Cipla on 26th August 2014 that Dr.Goswami says he had never seen such severe adverse reactions ever before.

I had appealed to Cipla to investigate drug Rokfos in the interest of Medical Science. In spite of my appeals, Cipla violated the legal provisions of Schedule 'M'. Whether they secretly withdrew the batch manufactured by them will forever remain a mystery. Maruti Nursing Home doctors withdrew the balance four injections from their stock. This is proved in the case against Dr.Mihirgiri Goswami at 15th Court, Mazgaon, Mumbai.

Cipla had to test only one sample from the batch. I had given batch number, manufactured date and expiry date. There was plenty of stock available with Cipla. They could have also taken one sample from Maruti Nursing Home itself.

There is no need for further proof that drug Rokfos was sub-standard and was given as a clinical trial to cure stiff neck in a single day.

This drug has to be given only once in a year for such serious diseases like hypercalcaemia of malignancy (cancer), bone metastates (cancer), multiple myeloma (cancer), Paget's disease of bone and post menopausal osteoporosis. Dr.Kakade's explanation to FDA, Goa that this drug was given for osteoporosis has been proven as false by Dr.Goswami's own admission in the e-mail **(Refer page 50)** that he gave Rokfos for joint pains and bone pain. Also at the meeting, transcripts of which are produced below he says that it was a one day admission **"Give today, Discharge tomorrow".** My wife was admitted for diagnosing the cause of stiff neck and MRI was the first line of action and not treatment with Rokfos for curing stiff neck in a single day. The patient's or relatives' consent was not taken prior to administering this drug IV Rokfos.

In the same para, the authorised Cipla representative says that in any event, their explanation has been accepted by FDA, Goa and has been adequately dealt with.

Cipla cannot decide whether the issue has been dealt with when the complaint was mine and I have every right to send rejoinders to both FDA, Goa as well as Department of Public Grievances, Government of Goa. This reply will also be sent to both authorities. Statements from Maruti Nursing Home doctors have to be taken by FDA, Mumbai and only then will the

issue be dealt with in the interest of Justice. Cipla cannot override FDA agencies at Goa and Maharashtra and put their credibility at stake. Besides there are criminal complaints for culpable homicide as well as complaints with Central Government Agencies.

e) As per this letter from Cipla dated 31 May, 2018, under page 3, Para 10 & 11, the serious adverse drug reactions were informed by Dr.Mihirgiri Goswami to Cipla Company representatives on August 7, 2014. They say that later they followed **Pharmacovigilance guidelines. This is again a false statement from Cipla.** Refer letter from **Indian Pharmacopoeia Commission** dated 24th November, 2017 **(Page 52)** addressed to me stating that the National Coordination Centre for Pharmacovigilance Programme of India does not have record of the adverse event of Rokfos – IV Infusion manufactured by Cipla. Pharmacopoeia Commission does not possess any other information in this regard.

f) The above false statements are proof that Cipla suppressed the ADRs for four years and are now lying to the concerned authorities. Accordingly all of their statements do not carry any weightage and value anymore. There was complete **FOUL PLAY** into manufacture and sale of sub-standard drug Rokfos in nexus with doctors of Maruti Nursing Home.

g) Both Cipla and Maruti Nursing Home did not report the ADRs to FDA, Maharashtra, Mumbai even though the death occurred in Mumbai itself.

h) Cipla Head-Pharmacovigilance has defended Maruti Nursing Home treating doctor on his wrong and faulty treatment. That this drug was given for treating osteoporosis. He also projected my wife as critically ill with one paralytic arm. This proves that Cipla is trying to defend sub-standard drug Rokfos as well as the treating doctor, Dr.Mihirgiri Goswami. This is conclusive proof of the nexus into sale of sub-standard drug IV Rokfos between Cipla Limited and Maruti Nursing Home.

i) Since Maruti Nursing Home is located in Mumbai and since Cipla headquarters is also in Mumbai, FDA, Maharashtra had to take action long time ago. My complaints to them were since early 2015. They have not

even questioned Maruti Nursing Home doctors on the serious adverse drug reactions. Neither have they questioned Cipla personnel.

j) The onus of responsibility rested with Cipla Limited to inform FDA, Mumbai and conduct quality test to prove that the batch was of standard quality.

k) FDA, Goa and Department of Public Grievances, Goa have been informed of the falsehood indulged in by Cipla representative. Also the doctors' statements are produced in my earlier letters. This reply from me will compound the total falsehood indulged in by Cipla personnel.

l) FDA, Goa has to take appropriate action against Cipla, Goa and cancel their manufacturing licence immediately. Also impose heavy penalties and compensation to the aggrieved party. Stringent action has to be taken for violating the drugs and cosmetics rules. Also for manufacturing batches of sub-standard drug Rokfos which was the cause of death of my wife. After all it was an untimely and unnatural death of an innocent caused due to criminal offences of unethical doctors and pharmaceutical company Cipla.

2. Cipla has chosen not to comment on the statements by the doctors of Maruti Nursing Home implicating Rokfos for the serious adverse drug reactions as well as the drug being given for curing stiff neck in a single day. Also on the Mediclaim doctor selling Rokfos to several hospitals and orthopaedics with full responsibility. Why did Cipla give him the responsibility and for what ?

- Reproduced below are the doctors' statements at the meeting. The treating doctor, Dr.Mihirgiri Goswami who is also the owner of Maruti Nursing Home has to respond whether the statements made by them in the meeting held on 22nd August 2014 were false or if the statements had come spontaneously based on facts that had transpired in their vendor-customer relationship. Audio CD can be given to Cipla representative if required to listen to the conversation from the doctors. The recording is very clear and all conversations between the doctors and relatives of the deceased are relevant to the issue only and related to drug treatment and death only.

Minute 07.10 to 08.15

OP1 > Osteoporosis ka aisa kuch blood test nahi atha hai. .....This this

Injection is basically a calcium binder. In general terms we say it is a calcium injection. It is a calcium binder matlab why it is given i will tell you. We give it to patients. I have given this to my mother also. We give it to patients and It is to be given for when calcium is sticking on the bones because the osteoporosis is like something like sand getting washed out on the river shore. Every year there is a calcium loss from the body. So before giving this injection we make sure that blood calcium level is normal. Blood calcium level has to be normal. Blood calcium level drops only when patient is not alive. So blood calcium has to be on the normal side only then we can give this injection. Because that is the only problem we face in this. It can cause a sudden drop in blood calcium. It can cause patient to have...

V > ***but It...is necessary to give ... this medicine. Was it necessary ?***

OP1 > ***Ya it was necessary in the sense because patient has multiple bone pains...***

V > She had pain only in the neck. She was admitted for traction.

OP1 > ***She had joint pain and obviously she was admitted only for a day because of stiff neck.***

Minute 08.40 to 08.55

OP1 > CIPLA people also gave me a call and they will never tell you it cannot be given when we are using it on a daily basis almost like a ....

V > *No Not on daily basis.*

OP1 > Cannot be given aisa aisa kaisa bol sakta hai ?

C > No. Did you take the precautions ?

OP1 > Precaution is to check the patient's serum calcium is normal or not..

Minute 09.20 to 09.30

OP1 > nai nai Indications me...everywhere It is used in a very high dose in cancer patients.

C > *Cancer patients.*

OP1 > It is given on a high dose and it is used frequently for us it is only

V > So it can be I ..... I can understand if she was suffering from cancer

we agree.

Minute 09.30 to 09.45

OP1 > I realise that but humlog ne kabhi aisa face nahi kiya problem we never faced this kind of problem we ..zoledronic acid given and patient had a problem as a direct co-relation we are we are...

Minute 15.30 to 15.40

C > Rokfos also you have advised ?

OP1 > Both are ICU places. This and This.

OP3 > I Don't know

Minute 40.35 to 40.55

C > This is from CIPLA ?

OP1 > Ya so we normally stock this injection just like our paracetamol and regular medical stuff which we give and it is not ki we see cancer patients everyday.

Minute 41.20 to 43.10

C > *What is this you are writing post zobone arthrolgy ? What is this word....*

OP1 > Joint pain

C > What is this

OP3 > Arthralgia A R T H

OP1 > joint pain which generally resolves in a day's time

C > So you knew after zobone this was there so you should have told told us No ?

OP1 > See it was it is a joint problem which joint pain suddenly people develop ... That is why I was telling you it acts on all the bones then it it fades away aisa nahi hai it it lasts for so long experience of giving that .....

Minute 43.30 to 44.30

C > *And you have charged 3500 instead of 2950. That again is a wrong practice.*

OP1 > Charges aisa wo ...

OP2 > ....procedure. This is not a simple injection sir this is not so simple

C > *Accha Theek hai bolo aap bolo*

OP2 > ...We have to take matlab wo jo bhi hai na...

C > You can sell above MRP? I have gone to department of metrology.

OP2 > We cannot sell we are purchasing as a stock . MRP is 2950 but for that Injection we have to charge 2000 3500

C > Why ?

V > Why ?

OP2 > This is a procedure. Proceure like ...

V > *Procedure kya hai*

C > I have gone to metrology department

OP2 > Nahi aisa kuch nahi hai usme

C > You have IV charges, ward charges separately . You have IV charges nursing charges separately so what other charges ?

That they said consumer forum

OP2 > For doctor you cannot say what other charges. Doctor has given the list Because this is a not so regular injection....

Minute 52.35 to 53.15

K > *Woh Rokfos ka jo 2950 ka 3500 kiya woh kisne kiya hai kisne, Inhone ?*

OP1 > Hum log wohi bol raha normally jo apna zobone aur rokfos yeh alag brand hai. Rokfos is a new brand, Our regular brand is Zobone which is actually costing 3500. By default yeh it is...

K > *Tho yeh galti hai*

C > No No No No zobone is rokfos rokfos is zobone.

OP1 > I am talking about MRP

C > No No

K > So you agree

V > MRP should not ...

C > Name medical term no

OP1 > He has done a mistake in not seeing the pamphlet. But overall generally if you write zobone it goes into 3500 category.

Minute 53.30 to 54.00

K > Tho aapne aapko laga ki aapne zobone diya but actually aapne rokfos Diya ?

OP1 > Nai laga aisa .... Everything is same. It is paracetamol marketed in 4-5 names. It is like that.

Minute 54.00 to 54.35

OP1 > I am telling you I have given this to my mother. That safe it is in all the case. Abhi yeh aisa turn out hoyega aisa kaun samje ga.

V > *Aisa turnout nahi hai*

C > So that means something has to be done about zoledronic acid.

OP1 > It is given very frequently that is why we are stocking it. *Nahi tho kyun hum log aisa. Aisa once in a bluemoon aisa ek patient deklega tho aisa zobone laganeka man me aaya de diya thodi aap ko laga M.R. kuch.....dekhe gaya tho main zobone laga dega aisa hai kya M.R.kuch.....deke gaya tho humlog rokfos prescribe karega aisa thodi hai.*

Minute 55.00 to 56.25

C > I will I will make a case on Cipla also that zoledronic acid is given just like that and people will die now ? So we have to

V > *Stop them*

C > Get stop that medicine.

OP1 > Abhi I am also afraid to give now. I will not give anyone. Abhi it has been given to my mother also you can understand so why I should be so much so much worried about it.

V > *..You just see to it we have to take action on this also.*

OP1 > Tho Iskeliye aaya tha mere paas mereko bola aap usko pass on karo. Mai tho bola ki please send it to you him by email. He was supposed to email it

to you.

K > Koi medicine diya itna effect hua uske liye kya steps lete ho aap log ?

OP1 > *Medicine ke baad ?*

K > Yeh effect hua, wrong effect

V > Itna effect hogaya

K > Kya kiya apne ?

V > Precaution

OP1 > We have to send it as a report to the company which they call...

K > Did you send ?

OP1 > Ya

K > Now you sent ?

OP1 > I have told that company fellow who comes to meet me us I told him. That's why he came up with this article no. He has come up with all these articles see zoledronic acid....

K > *Now you said when he phoned that's why he...*

V > Baad me aaya na baad me hai na.

OP1 > Usse baat kiya ki aisa hai they to report it as adverse reaction. Its called adverse reaction matlab patient ko kabhi aisa woh log ko bhi malum nahi kabhi aisa hota hai we have to report it and they have to take steps ....

V > So this is a unique case ?

OP1 > That's what. There are a lot of things which are reported like this and they stop ....

Minute 58.10 to 59.00

OP1 > Change aisa kuch tha hi nahi aisa kuch, and this is definitely one very rare reacton with zoledronic . That is that is what. You are also right bhai. We are also shocked ki aisa .....

C > *So it needs.....*

V > We should ban this drug.....according to you.

OP1 > There are drugs which are banned like that...

V > So In other words we have to ban this drugs now

OP1 > Some pain killers which are found which were very frequently given to

pregnant ladies ultimately they....

V > Samajh gaya. Pregnant ladies leave aside we are talking about this particular case.

OP1 > I am saying you how they how these companies ultimately get these reports, adverse reaction ka report aake. Ultimately they put a ban on this thing.

Hour 1.14.00 to Hour 1.14.40

OP1 > Barah saal me, barah maine me ek do dete hai. Barah maine me ek do Dete, usme aisa kuch sawaal hi nahi

***K** > Usme reactions samajtha hai ?*

C > You mean to say ?

OP1 > Bahut, bahut rare, very

K > Rare hai, but hai na

C > Hogaya na ?

K > Hua na ?

C > Mar gaya na ?

OP1 > It is not, not at all given anywhere. It is to be reported.

***V** > It is not ...*

K > Have you reported ? Have you reported ?

OP1 > Cipla has reported as adverse reaction.

Minute 1.16.30 to 1.17.20

OP1 > Utna aisa very very very yeh for us also ke baba Aisa kaisa yeh...

C > So you mean to say yeh zoledronic acid aap kisiko bhi denge ?

OP1 > Abhi tak aisa hua hi nahi hai.

K > This is the first case isliye

OP1 > Zoledronic diya aur aisa hogaya matlab abhi bhi...

C > That means that drug needs to be investigated ?

V > It is to be stopped in India .all over the world then It has caused death yaar.

OP1 > Zoledronic acid se aisa hoyega wo kisiko hum log kisiko aisa even rare suspicion bhi rahega tho kyun dega ?

V > Cipla hum log leke aayenge aur batayenge it has to be stopped aap bolo stop karo

OP1 > From a simple neck pain patient why why we wanted to yeh keep quiet ?

V > Hum log wohi tho puchta hai. Hum log puch raha hai kyun diya ?

OP1 > Hum log kabhi deta hai ki ek din. One day admission plan karke diya tha aaj diya aur kal discharge ho jayega.MRI bhi plan nahi kiya Tabhi tho on admission MRI nahi hai.

Hour 1.59.00 to 1.59.20

OP2 > Aap dekhiye main unka favour ki baat nahi kar raha hoon sir kyun ki mai mai pacchis jagah jaata hoon aisa kuch baat nahi hai yeh jo rokfos injection hai na mai orthopaedic teen doctor ka yahan jaata hoon, teeno jagah whole responsibility se deta hoon aur mera target sirf yeh nahi ki patient ko takleef ho ya doctor ko, dono balance karke chalna hota hai mujhe, kisiko takleef nai ho.

V > kahan pe cervical spondilytis me aapne diya hai aisa suna hai kabhi ?

OP2 > Orthopaedic bone ke takleef me abhi wahan pe doctor Radhe sahab hai **unke yahan bhi yeh zoledronic injection ka regular ....hota hai**

C > ...tho teek hai abhi yeh malum padgaya ki yeh common....

OP2 > commonly use karte hain

C > tho abhi zoledronic acid pe apneko complain karna padega

OP2 > **....dr.saab ... hai.....aap naam sune honge abhi tho expire huye ek maine pehle wo unke yahan bhi regularly do box na roz pandhra injection lagta ....pandhra bees injection roz....pura stock ka stock atha tha**

K > wo jaroorat rahega wo patient ka, aise hi nahi diya rahega

OP2 > ....aur unke yahan Kolhapur aur kahan kahan se log aathe hain .... ke liye...

K > tho unke paas jo patient the unka jaroorat raha rahega ....

a) Hours 1.59.50 to Hour 2.00.20

OP2 > bone support ke liye bone support ke liye yearly ek injection aisa or commonly hi dete hai, yahan doctor ke paas hota hai aisa nahi hai, teen char jagah orthopaedic ke paas jatha hoon, sabme deta hoon, Isme aisa itna dramatic allergy ya reaction ho sakta hai aisa maine bhi nahi dekha tha

K > yeh Hota hai reaction shanti se baitne ka ? correct hai ?

reaction hota hai shanti se baitneka ?

OP2 > Nahi shantise kyun baitoon ... ?

K > tho wo inka galti hai na ?

Minute 2.21.20 to 2.21.45

K > Abhi aapko, abhi aapko pata chala hai because of this medicine one death has happened,

OP1 > Ya

K > what have you done ? have you immediately...

OP1 > I have reported, I have reported to their person, the medical advisor and and...

3. As far as Cipla Global CEO and MD and Head-Pharmacovigilance is concerned,

a) Please refer to my E-mail to the Global CEO and MD of Cipla dated 18th April, 2017. I had received a reply "Thank you for notification" "We acknowledge receipt of this e-mail" "We will take appropriate action". This goes to prove that the said Global CEO and MD was in charge at that time and failed in his responsibility to address the serious grievance of a Cipla consumer regarding their drug causing his wife's merciless, unnatural and untimely death.

b) The Head-Pharmacovigilance has been repeatedly referred to in my recent communications based on relevant points of false, baseless, defamatory and maligning remarks on my wife's health condition prior to being administered Cipla drug Rokfos. He has lied to the Director of Food and Drugs Administration, Goa without producing any proof of his disgusting remarks. This was like adding Salt to Injury after Cipla drug caused her death. The Global Head-Pharmacovigilance should have restricted himself to whether Rokfos caused ADRs or not. There was no need for defamation with ulterior motives to deceive the Director of FDA, Goa that the death of my wife was not due to Rokfos and that she was critically ill with paralysis and spinal tuberculosis. He as well as Cipla Management have to tender an unconditional apology.

c) Failure to respond to your consumer's repeated appeals for four years on Cipla drug causing his wife's death was mental torture to the aggrieved party. Cipla Global CEO and M.D. should have responded to my appeal. Also false, outrageous, and baseless nature of remarks by Cipla Head–Pharmacovigilance was disgusting to the relatives of the deceased.

4. Cipla is drawing attention to my letter of April 18, 2017 in which I said "I am not accusing Cipla in any manner" That they are perplexed by my abrupt change of tactic to unlawfully allege and defame the Company before the Hon'ble food and drug authorities and governments, four years after the sad demise of my wife. That it is my attempt to coerce the Company to give in to my illegal demands.

- There was no tactic on my side. I was only pursuing the truth and seeking justice for death of my wife due to Cipla drug Rokfos. Little did I realise then that I was requesting the **Main Accused** for information. Foul tactics and blatant falsehood of the real culprit **"Cipla"** now stands totally exposed for the entire world to see.

- There is also no change in tactic from my side. I have found out the truth into suppression of the serious adverse drug reactions of Rokfos by Cipla, thanks to the Office of Director General of Health Services, New Delhi who advised me vide letter dated 20/12/2017 of the responsibility of drug manufacturing companies into complaints received of their defective products and reports of serious adverse drug reactions **(Refer page 53).**

- I have not complained after four years. My complaints to Cipla were since **16th August 2014**. My complaints are still continuing. Now against the real culprits Cipla and Maruti Nursing Home. Till I get justice, I will not relent.

- My complaint to FDA, Maharashtra, Mumbai was on 28th April 2015 which is continuing till this date.

- My complaints to the Hon'ble food and drug authorities and governments had started soon after the death of my wife. It was in the year 2014 that the Directorate General of Health Services had sent me indications of use of Zoledronic Acid.

- My complaints are to all food and drugs and other government authorities including the PMO, Chief Minister of Maharashtra and Minister for Consumer Protection and FDA.

- This was after the Office of the Drugs Controller General of India advised me of the legal provisions of Drugs and Cosmetics Rules, Schedule M.

- It is not my attempt to coerce the Company to give in to my illegal demands. My demands are justified to bring the culprits to book.

- It is my right to seek justice for death of my wife due to Cipla drug which was sub-standard and was given as a clinical trial to cure stiff neck in a single day. These facts are revealed by the doctors of Maruti Nursing Home themselves as has been elaborated by me in my earlier letters and complaints to Food and Drug Control and other Government Authorities.

- My attempt is to bring the attention of the Government and especially the Honourable Prime Minister Shri Narendra Modiji who is very much concerned about the nexus between doctors and pharmaceutical companies.

- It is my attempt to educate the entire nation of the unethical malpractices existing in the pharmaceutical industry. People should be made aware of their rights and seek their grievances with the authorities.

- My attempt is to involve elected MPs and MLAs to address issues regarding malpractices by doctors and pharmaceutical companies by raising this issue in the Parliament and State Assemblies so that the lacuna in the system can be rectified by bringing in amendments to existing laws.

- That consumers do not have to run after authorities in different states in pursuit of their cases. The new Consumer Protection Bill, 2018 can include issues to protect the common consumer from malpractices by pharma companies in nexus with doctors.

- **My last letter to Cipla Global CEO and MD had stated the following points:**

a) **I am not accusing Cipla in any manner –** Till that point of time I had not accused Cipla in any manner as I was only interested in pursuing my case

against the doctors. It was on receipt of letter from Directorate General of Health Services dated 20th December 2017 which made me aware of Schedule M of the Drugs and Cosmetics Rules which solved the mystery into "Suppression of the Serious Adverse Drug Reactions" by all concerned and especially drug manufacturer Cipla Ltd. The facts of the case had been presented by me to Department of Pharmaceuticals, CDSCO, DGHS and Office of Drugs Controller General of India. Only after they went through complete facts in my complaints did they ask the concerned authorities to investigate into the nexus between Maruti Nursing Home and Cipla Ltd into sale of sub-standard drug IV Rokfos. They have also mentioned that the letter has been issued with the approval of the competent authority.

Other points in my last e-mail to Cipla Global CEO and MD were :

b) 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. ***It is surprising that Cipla chose not to answer me then.***

c) What is the reason that Cipla did not investigate into their drug Rokfos causing severe adverse reactions ultimately leading to the patient's death ?

d) Why did Cipla not inform FDA or CDSCO about these rare disorders ultimately leading to death ?

e) Was it because of bad publicity or to protect Dr.Goswami who failed to take action as the drugs were sold illegally ?

f) Or was the drug really sub-standard ?

g) There is no information forthcoming from CIPLA, FDA, Maruti Nursing Home as also other hospitals involved in the treatment.

- ***Can Cipla respond why they chose not to reply to the above questions a) to g) especially when I had questioned whether their drug was really sub-standard ?***

5. Cipla is questioning now whether Rokfos was given or Zobone was given ? It was me who had advised Cipla about the confusion between Zobone and

Rokfos. Anyway the confusion is cleared now by Cipla themselves admitting that Dr.Mihirgiri Goswami informed them on August 7, 2014 about the ADRs. That they had immediately informed the concerned licensing authority.

- Cipla instead of investigating about their drug causing the ADRs sent me Indications of use of Rokfos.
- The doctors tried to deceive me that these were known side effects and that they were not responsible for the death.
- Cipla being an International Pharmaceutical Giant would not have treated allegations on their drug causing serious ADRs resulting in death so casually. It is obvious that Foul Play was involved.
- Would a small nursing home make an allegation on an international drug company so casually and get away with it unless they were involved with the company in their malpractices.
- The original box of Rokfos was attached to in-patient medical records immediately.
- It was all the more important for Cipla representative to check especially since this drug had caused a death.
- The treating doctor has however clarified in his statements at the said meeting on 22nd August 2014 that it was all same. Zobone or Rokfos. Just like paracetamol marketed in different brands. His contention was that if the doctor prescribes a medicine, the nurse can administer any of the several brands available if the strengths are same.
- In his statements to the Maharashtra Medical Council, Dr.Mihirgiri Goswami has stated that the drug did not suit the complainant's wife and hence he discontinued the same. That the nurse has inadvertently written Zobone instead of Rokfos.

6. For the past four years my grievance **addressed to Cipla only** was solely against Maruti Nursing Home. However civil and criminal cases have been filed by me against Maruti Nursing Home as given below.

It would be advisable for Cipla to forward my referenced letters to Maruti Nursing Home. A whole lot of clarity will emerge from the response by Dr.Mihirgiri Goswami especially on treatment given to cure stiff neck in a single day.

My complaints against Maruti Nursing Home are with :

a) Maharashtra State Consumer Disputes Redressal Commission. At that time, I had no information about Schedule M of Drugs and Cosmetics Rules which Cipla had violated.

b) Else Cipla would have been the main accused in selling sub-standard drug to a consumer. Hence the complaints to drug control authorities and the Mumbai Police for necessary action. Cipla personnel have to be held responsible. Cipla has to pay the penalty for causing death of my wife.

c) Maharashtra Medical Council.

d) Police Complaint with Navghar Police Station, Mulund, Mumbai in which Cipla is an accused. This complaint has been forwarded to Directorate of Health Services, Mantralaya, Government of Maharashtra.

e) The Prime Minister's Office.

f) FDA, Maharashtra, Mumbai. However, I have accused FDA, Mumbai officials with the PMO for colluding with Cipla and Maruti Nursing Home. The matter has been forwarded to FDA, Maharashtra but I am not getting replies to my allegations since the past several months.

g) Similarly, response to my grievances has been sought by Chief Minister's office and office of Minister for Civil Supplies, Consumer Protection and FDA from the FDA Joint Commissioner. There is however no response.

h) Ultimately the matter will be raised by elected representatives of the State and the case will be handed over to the CBI.

7. Other points in letter from Cipla dated 31 May 2018 (pages 2 to 6) :

Para 1: The nexus is proved elaborately in the above paragraphs.

Para 2: FDA, Maharashtra did not forward my complaint to FDA, Goa.

My grievance to PMO is basically against FDA, Mumbai officials for colluding with Cipla Limited as well as Maruti Nursing Home and not taking any action.

FDA, Maharashtra, Mumbai have still to respond to my complaints against the FDA officials. Maharashtra Government officials have asked the FDA, Commissioner to respond.

Cipla cannot decide on who will investigate Cipla and decide themselves that the issue has been dealt with. They cannot erode the credibility of Food and Drugs Administration, Government of Goa.

This is not a frivolous issue. Even though Cipla is an International Company, they are not above the law of the land and have to face the consequences for criminal offences involving death of a consumer from their sub-standard drug in connivance with unethical doctors.

It is interesting to note that as per Cipla, Goa, handling of product complaint and complaint related to ADR are investigated by Drug Safety Department, Cipla, Mumbai and not Cipla Goa location **(Refer Page 46),** letter received from FDA, Goa.

FDA, Mumbai officials need to take note of this and take action against Cipla immediately for death caused from Cipla sub-standard drug Rokfos. The onus is on Cipla to prove that Rokfos was of standard quality.

Para 3: The nexus into sale of sub-standard drug is proved by me in paragraphs above. Standard quality of a drug causing death had to be reported to the concerned licensing authority and proved by Cipla after Dr.Mihirgiri Goswami informed them on August 7, 2014.

Para 4: I had raised the issue with Department of Public Grievances, Goa as FDA, Maharashtra were not acting on my several complaints to them on the serious ADRs. They have still not taken action against Cipla nor against Maruti Nursing Home on the serious ADRs. Why is Cipla afraid of investigation by FDA, Maharashtra. Will Dr.Goswami reveal all just like he revealed to us in the said meeting on 22nd August 2014. In any case FDA, Mumbai officials are themselves under scrutiny for colluding with Maruti Nursing Home as well as Cipla Limited.

Para 5: FDA, Goa has not completed its investigation. If it is so, it will be a one-sided discharge without giving reasons for discounting facts and evidence produced by me. It is a question of their credibility. Cipla cannot erode that. My allegations of faulty manufacturing practices were based on Media reports (Economic Times, PTI, etc) **(Refer pages 54-57).**

Para 6: The allegations and contentions in the letter dated May 9, 2018 are all true. The company has not given any assistance to my repeated appeals to them. I did not realise then that a pharmaceutical giant would be involved with an unethical nursing home in malpractices. The reasons for not taking any action to my several e-mails by Cipla was because of the fact of their complicity in sub-standard drug sales along with Maruti Nursing Home. I have put the blame on the company after I was informed of Schedule M of the Drugs and Cosmetics Rules. Cipla explanation to FDA, Goa with false statements is now with the Director of FDA, Goa. I expect quick action against Cipla. I have also included Cipla in my criminal complaint against all accused for causing death of my wife.

The company's senior management have to be made aware of the malpractices by their personnel. It is they who are answerable to the shareholders and the consumers. My matter will never be addressed by Cipla personnel unless taken at a higher level.

The same will hold good if FDA, Maharashtra fails to take action against Cipla as well as Maruti Nursing Home. CBI will have to be involved.

Para 7: Unless there was **FOUL PLAY** involved, Cipla would have not violated Schedule M of the Drugs and Cosmetics Rules. FDA, Goa visited Cipla Goa manufacturing plant in 2018. The substandard drug which caused my wife's death was produced in 2014. Why did Cipla keep quiet for four years ? They say that they had addressed my concerns. Can they provide material to prove their claims as is being done now but with totally false statements.

If Rokfos was given for treating stiff neck in a single day, was it not a **clinical trial** ? Mediclaim doctor claiming that he gave Rokfos with full responsibility to ensure that neither patient had a problem nor the treating doctor clearly proves that these were specially manufactured batches given to Maruti Nursing Home. Else who is the Mediclaim doctor to take responsibility of a drug manufactured by an

international pharmaceutical company. Hence Cipla did not test the batch for standard quality. Hence Maruti Nursing Home withdrew the remaining injections from their stock.

Para 8: Suppression of the serious ADRs and violation of Schedule M is a serious matter and definitely a criminal offence.

Producing facts before the concerned authorities for seeking justice cannot be called intimidation.

Threatening to file defamation case for submitting facts to concerned authorities seeking justice for an innocent life lost due to criminal offences is called intimidation to withdraw my complaints with the authorities. The same pressure tactics was used by Dr.Mihirgiri Goswami.

Para 9: I am aware that Cipla is a well-known pharmaceutical major. I differ about quality of Rokfos which caused such drastic adverse drug reactions never seen ever before as told to me by several experienced doctors at Jupiter Hospital. Suppression of the ADRs and withdrawal of the remaining injections at Maruti Nursing Home shows Cipla's policies and methods of doing business are unethical.

Malpractices by international pharmaceutical giants have been since time immemorial. I am only concerned with sub-standard drug Rokfos which took my wife's life mercilessly.

Besides as mentioned in my earlier letter (with calculations) the price paid by me for Rokfos was over 500% of cost to Cipla. This is definitely unethical selling practices which will be addressed by the Government in the new pharmaceutical policy.

Cipla has not offered me any assistance as obviously they were at the helm of the disaster that took my wife's life. I had offered to meet them in my e-mails. They refused to meet me which proves that foul play was involved which should be penalised heavily.

Which statutory procedures did Cipla follow ? Did they follow Schedule M ? Did they inform FDA about the ADRs ? Did they inform National Pharmacovigilance ?

It is highly ironical for Cipla to say that the treating doctor did not raise any concerns as to the quality of the product. He has said "Abhi yeh aisa turnout

hoyega, yeh kaun samjega" "Abhi I will also not give now". Also withdrew the remaining injections from his stock. The most crucial question is **Why did Cipla violate Schedule M even after being repeatedly informed by me to investigate in the interest of Medical Science ?**

Para 10 & 11: It is not a desperate attempt to somehow impute liability to the company. Cipla has to pay the price for its criminal offences. That Cipla carried out investigation has been proved false in the paragraphs above. The proposed new pharmaceutical policy measures have to be imposed on Cipla which means a marketing ban for one year, confiscation of all top most brands of its products and distributed to Government-run hospitals, hefty fines, compensation to the aggrieved party and also jail terms for personnel involved.

Para 12: The nature of death would be recorded in the death certificate. Certainly Cipla personnel are in touch with the shameless doctors to ask for death certificate. It is advised that Cipla consult Dr.Mihirgiri Goswami on his Discharge Card which was blank. Rokfos caused severe blood disorders resulting in Aplastic Anaemia or bone marrow failure at Maruti Nursing Home itself which was the cause of death. Refer E-mail from Dr.Goswami **(Page 49)** where he says "We are aware of the sad demise of Mrs. Kamini Barkur following diagnosis of Aplastic Anaemia leading to complications."

Para 13: Ambiguity on whether Zobone or Rokfos was administered has been clarified by Cipla themselves under Para 14, f, page 4 of their letter. Dr.Goswami informed company representatives who followed a procedure in speaking on telephone **(TRF)** with treating doctor. What did they talk about ? ADRs ? Zobone or Rokfos ? or paralytic arm ?

Para 14:

a) My first e-mail dated 16/08/2014 had reported that the death **was drug induced.** There is no lack of certainty on Zobone or Rokfos. It is confirmed by Cipla under Para 14, f, page 4 of Cipla letter.

b) Cipla is again confirming that the treating doctor did mention ADRs but declined to fill in the ADR Form as death was not drug related.

Whether it is death or not, Schedule M has to be followed by drug manufacturing companies. It had to be reported to FDA.

It is this very point that FDA, Mumbai officials have to be made responsible for not acting against Maruti Nursing Home doctors for illegal sale of drugs causing grievous hurt within the meaning of Schedule 320 of the IPC.

Cipla also has to be made liable for selling sub-standard drugs and after the serious ADRs they chose to suppress the same from the concerned licensing authority. The remaining injections were withdrawn at Maruti Nursing Home. My first e-mail dated 16/08/2014 had reported that the incident was drug induced.

c) The indications of use of Zoledronic Acid were sent to me when I reported the ADRs to Cipla. This was given to me by Dr.Mihirgiri Goswami at the said meeting on 22nd August 2014 and both the doctors revealed that they had never seen such drastic ADRs ever before.

d) All along we are talking of ADRs only. Cipla has accepted the ADRs. Bone marrow failed after petechial rashes (bleeding from under the skin) and pancytopenia (drop in all three blood counts). Petechial rashes and pancytopenia are typical symptoms and characteristic features of Aplastic Anaemia. Both were side effects of drug Rokfos which was sub-standard.

e) My contentions of faulty manufacturing practices reported by US FDA are from media reports **(Refer pages 54-57).** It definitely has a relevance in the death of my wife as Rokfos was manufactured at Goa and Cipla did not check the batch deliberately after the ADRs.

f) The issue under this para has been dealt with by me in earlier paragraphs. Under any circumstance there can be no way that the drug control authorities both at the Centre and the States can pardon this merciless, unnatural and untimely death. There will be havoc created by drug manufacturing companies if violation of Schedule 'M' is a pardonable offence. There will be more deaths and the consumers will have no redressal. The Parliament will have to be apprised of this lacuna in the system.

g) As per Cipla, they have recorded the telephonic call with the administering doctor on August 7, 2014 at 14:58 hours regarding spinal tuberculosis, paralytic arm and one shot of steroid and have maintained the same.

It is surprising that while Cipla has been saying that they had co-operated with me in providing all information, the above crucial information was not given to me. Cipla saying that they immediately informed the appropriate licensing authority of the adverse event has been proved false by letter from FDA, Goa. Can Cipla now produce TRF before the Director of Health Services, Mantralaya, Government of Maharashtra ?

h) The fact that Cipla has defended the treating doctor that he administered Rokfos for osteoporosis shows that they are in nexus in defending the drug Rokfos which was sub-standard.

Para 18 & 19: The onus of proving that Rokfos manufactured at Cipla, Goa plant (which caused serious adverse reactions) was of standard quality had to be proved by Cipla immediately on August 7, 2014 when Dr.Mihirgiri informed them of the ADRs.

IV Rokfos may be used by thousands of people but the issue now on hand is death caused due to serious adverse drug reactions of Rokfos. We are talking about this particular batch sold to Maruti Nursing Home and which was the cause of my wife's death.

Cipla suppressed the serious adverse reactions and is blatantly ridiculing Schedule 'M' of the Drugs and Cosmetics Rules. Is Cipla above the office of the Drugs Controller General of India ? Is Cipla above the Food and Drugs Administration ? Is Cipla above the law of the land and can escape punishment for criminal offences ?

The false information given by Dr.Kakade requires unconditional apology. Cipla had to be concerned only with ADRs of their drug. The health condition of the patient and the cause of her death is not relevant to Cipla. It will be decided at the Maharashtra State Consumer Disputes Redressal Commission.

The death of my wife may be a frivolous issue to Cipla personnel but not to the aggrieved party. The Laws of the land has been put in place and Cipla has to pay the penalty for causing death of my wife from their sub-standard drug.

The entire rank and file of Cipla is involved in falsehood, malpractices, unethical selling practices and causing death by manufacturing sub-standard drugs. After the killing they indulge in defamation and maligning the victim, resorting to using underworld words like extortion.

I have asked for unconditional apology for defamation of my wife's health condition without producing proof of TRF. Else I will file defamation cases which is legitimate after Cipla drug caused her death. Even if the disgusting remarks were used by Dr.Goswami, there was no need for Dr.Kakade to misguide FDA, Goa that the ADRs did not cause my wife's death. Using words like egregious will not scare me. Threats and pressure tactics have been used before also. I have taken precautionary measures.

The death was for monetary gain by Cipla by manufacturing sub-standard drugs. Cipla has no moral ground left after the exposure and are at their wit's end to defend themselves and hence the innumerable false statements. I have consulted several pharma activists and consumer activists. The opinion is that Cipla cannot get away after causing this death.

8. Nexus between Cipla and Maruti Nursing is proved in the aforesaid paragraphs. Maruti Nursing Home withdrawing the remaining four injections from their stock clearly proves that this batch was sub-standard.

There are no false and frivolous allegations by me before the state and central authorities. All the allegations are based on facts by producing hard evidence.

On the contrary, Cipla has lied to the Food and Drugs Administration, Goa. They did not produce evidence that they had informed FDA, Goa about the adverse reactions after receiving information from Dr.Goswami on 7th August 2014. They have stated it now but it has been proved as false.

The nexus is proved beyond doubt after the defamatory and maligning remarks by Dr.Kakade to FDA, Goa to project my wife as having been critically ill prior to administration of drug Rokfos from Cipla. He is also supporting

Dr.Mihirgiri Goswami on his wrong and faulty treatment with Rokfos. The treating doctor has said that he gave Rokfos for multiple joint pains and bone pain. Dr.Kakade says that he gave the medicine for osteoporosis.

That Cipla induced the doctors of Maruti Nursing Home to promote Rokfos to other hospitals and nursing homes is based on the following statements by the doctors. It was Dr.Mihirgiri Goswami and Dr.Dubey who have told on record :

"Hum log wohi bol raha hai, normally jo apna Zobone aur Rokfos yeh alag brand hai. ***Rokfos is a new brand, our regular brand is Zobone".***

"I am telling you I have given this to my mother. That safe it is in all the case. Abhi yeh aisa turn out hoyega aisa kaun samjega"

*"****Abhi I am also afraid to give now****. I will not give anyone. Abhi it has been given to my mother also you can understand so why I should be so much worried about it"*

"Koi medicine diya itna effect hua uske liye kya steps lete ho aap log ?"

"We have to send it as a report to the company"

"Did you send ?"

"I have told that company fellow who comes to meet me *us I told him. That's why he came up with this article no. He has come up with all these articles see zoledronic acid".*

"Usse baat kiya ki aisa hai they have to report it as adverse reaction*. Its called adverse reaction matlab patient ko kabhi aisa woh log ko bhi malum nahi kabhi aisa hota hai we have to report it and they have to take steps"*

"So this is a unique case ?"

"Change aisa kuch tha hi nahi aisa kuch, ***and this is definitely one very rare reacton with zoledronic.*** *That is that is what. You are also right bhai. We are also shocked ki aisa"*

"I am saying you how they how these companies ultimately get these reports, adverse reaction ka report aake. Ultimately they put a ban on this thing"

"Have you reported ? Have you reported ?"

"Cipla has reported as adverse reaction"

*"**From a simple neck pain patient** why why we wanted to yeh keep quiet ?"*

"Hum log wohi tho puchta hai. Hum log puch raha hai kyun diya ?"

*"Hum log kabhi deta hai ki ek din**. One day admission plan karke diya tha** aaj diya aur kal discharge ho jayega. MRI bhi plan nahi kiya Tabhi tho on admission MRI nahi hai"*

*"Aap dekhiye main unka favour ki baat nahi kar raha hoon sir kyun ki mai mai pacchis jagah jaata hoon aisa kuch baat nahi hai. yeh jo Rokfos injection hai na mai orthopaedic teen doctor ka yahan jaata hoon, **teeno jagah whole responsibility se deta hoon aur mera target sirf yeh nahi ki patient ko takleef ho ya doctor ko, dono balance karke chalna hota hai mujhe, kisiko takleef nai ho".***

*"bone support ke liye bone support ke liye yearly ek injection aisa or commonly hi dete hai, yahan doctor ke paas hota hai aisa nahi hai, teen char jagah orthopaedic ke paas jatha hoon, sabme deta hoon, **Isme aisa itna dramatic allergy ya reaction ho sakta hai aisa maine bhi nahi dekha tha"***

"Abhi aapko, abhi aapko pata chala hai because of this medicine one death has happened"

"Ya"

"what have you done ? have you immediately"

"I have reported, I have reported to their person, the medical advisor and.."

Cipla says that Applicable provision of Schedule M of the Drugs and Cosmetics Rules is related to reporting to the licensing authority, which the company has complied with in having informed the DCGI (the appropriate licensing authority), the Pharmacovigilance Program of India and later FDA, Goa.

As per letter from Director General of Health Services **(Refer page 53),** they have said that reports of serious adverse drug reactions resulting from the use of a drug along with comments and documents shall be forthwith reported to the concerned licensing authority which was FDA. This was followed with

letter from the office of the Drugs Controller General of India who have reiterated the same **(Refer pages 47-48).**

As per Schedule 'M' clause 27.1 **(Refer page 58),** a prompt and effective product recall system of defective products shall be devised for timely information of all concerned stockists, wholesalers, suppliers up to retail level within the shortest period.

Clause 27.6 says that the recalled products shall be stored separately in a secured segregated area pending final decision on them.

Cipla had to recall their drugs as per Schedule 'M' to get them checked for quality. Forget about recalling the drugs from the market, they did not even check one sample available with Maruti Nursing Home or from their own stock which was manufactured just six months back.

They were very much aware of their quality. That these were specially manufactured batches for treating minor bone problems as revealed by the doctors at the said meeting on 22nd August 2014. The said batches would have failed the quality tests and the clinical trials would have been exposed.

Cipla did not comply with reporting to the licensing authority as claimed by them. Refer letter from FDA, Goa **(Page 46)** and letter from Indian Pharmacopoeia Commission **(Page 52).** Cipla is lying blatantly.

I have never claimed that IV Rokfos was subjected to clinical trial in 2014 or earlier. I have stated based on the faulty treatment by the doctors of Maruti Nursing Home for stiff neck, joint pains, etc. that these were specially manufactured batches for minor bone problems which is **"Clinical Trial".** Rokfos indications of use does not mention stiff neck or joint pains. This is the reason for my claim that Rokfos was given as a Clinical Trial. That the ADRs being of such disastrous effect and dire consequences within 20 hours of the drug being administered proves that it was sub-standard. Deliberate failure to check the samples for quality confirms that Rokfos batch was sub-standard.

Cipla has not been empathetic enough with me and have not provided with any information as requested.

- The only information provided to me was the indications of use sent to Maruti Nursing Home. Maruti Nursing Home with Cipla's booklet tried to deceive the relatives of the deceased about the known side effects that occurred in the case of my wife and that the doctors were not responsible.

- Since August 2014 till April 2017, I have been appealing to Cipla Management to investigate Rokfos in the interest of medical science.

- The following were replies from Cipla :

  "Thank you information".

  "Thank you for notification".

  "We acknowledge receipt of your e-mail" "We will take appropriate action"

There was no action. All actions claimed by Cipla to have been taken by them are rebutted with proof of false statements.

9. All the accused viz. Maruti Nursing Home treating doctor, Dr.Mihirgiri Goswami and Cipla personnel have mentally tortured me with false information, maligning the deceased with disgusting remarks on her health condition prior to Rokfos being administered, threats to file defamation cases, etc. I have been mentally tortured since four years.

However, I have satisfaction that I have reached the bottom of the truth and hope that action will be taken by Mumbai Police and Charge-Sheet filed at the earliest.

10. Drug control authorities (FDA) in both states of Maharashtra and Goa as well as CDSCO and DCGI should take the most stringent action against Cipla. This should be in the form of actions already envisaged and proposed by CDSCO to amend the Drugs and Cosmetics Act, 1940 making pharmaceutical companies pay penalties for drugs causing ADRs and jail terms with hefty fines. Draft proposal for changes in the new pharmaceutical policy as reported in sections of the media **(Refer pages 59-63)** include the following penal actions :

a) A marketing ban on the pharma company for a year.

b) Confiscation of the top most brands of the company's products and distributed to government hospitals.

c) Hefty fines running up to Rs.10 crores and above depending on the severity of the offence committed.

d) The matter is not frivolous as claimed by Cipla but it is a case of death caused by sub-standard drug and suppression of the crime for four long years. It is similar to serious crimes like murder, terrorism, etc.

11. Finally, I am awaiting an unconditional apology from Cipla Management for false, defamatory, maligning and baseless information on the health condition of my wife prior to drug Rokfos being administered to my wife. This after drug Rokfos was responsible for her death.

Yours Sincerely,

Umeshchandra Barkur

A-15, Neeta Apartments,Chaphekar Bandhu Marg,

Mulund East, Mumbai 400081. Cell : 98201 17923

Cc: Director, Directorate of Food and Drugs Administration, Goa.

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

Cc: Joint Commissioner, Food and Drugs Administration, Greater Mumbai.

Cc: Directorate of Health Services, Mantralaya, Government of Maharashtra.

Cc: Office of Drugs Controller General of India, FDA Bhavan, Kotla Road, New Delhi-110002.