Date : 21st December 2020

Shri J Ashok Kumar IAS
Secretary To Chief Minister
Office Of Secretary To Chief Minister , Government Of Goa ,Secretariat,
Porvorim ,Goa 403501

Dear Sir,

SUBJECT : COMPLAINT AGAINST DIRECTOR OF FDA GOA FOR COLLUDING WITH CIPLA LIMITED IN DEATH OF MY WIFE FROM DRUG ROKFOS MANUFACTURED AT GOA FACILITY.

Further to my e-mail sent today, I am enclosing my book on "Cipla Drug Trial".

This is my complaint to the hon'ble Chief Minister of Goa against FDA Goa Director for colluding with pharma company Cipla Limited in the matter of death of my wife from serious adverse drug reactions of injection Rokfos manufactured at Cipla Goa facility.

1. At the outset,
   a) Cipla did not follow statutory guidelines meaning Schedule 'M' of Drugs and Cosmetics Rules which mandated that all complaints regarding product quality shall be carefully reviewed and recorded according to written procedures by the manufacturing companies. Each complaint shall be investigated/evaluated by the designated personnel of the company and records of investigation and remedial action taken thereof shall be maintained. There shall be written procedures describing the action to be taken, recall to be made of the defective product. Reports of serious adverse reactions resulting from the use of a drug along with comments and documents shall be forthwith reported to the concerned licensing authority. **[Exhibit FDAGOAPAGE1 of FDA GOA EVIDENCE DOCS][attached].**
   Cipla violated Statutory guidelines of Drugs and Cosmetics Act, 1940 and Rules thereof.
   b) As per FDA Goa, handling of product complaint and complaint related to ADR are investigated by Drug Safety Department, Cipla Mumbai and not at Cipla Goa location. **[Exhibit FDAGOAPAGE4 of FDA GOA EVIDENCE DOCS]**
   c) Cipla did not report the serious ADRs to concerned authorities viz. FDA Goa or FDA Maharashtra, Drugs Controller General of India (DCGI) and Pharmacovigilance Programme of India (PVPI) for four long years.
   d) My complaint with PG cell of government of Goa was forwarded to FDA Goa.
   e) FDA Goa Director issued a show cause to Cipla and sought explanation from the company. **[Exhibit FDAGOAPAGE17 of FDA GOA EVIDENCE DOCS].**
   f) There could be no investigation by FDA Goa in 2018, four years after the death of my wife in 2014.
   g) There could be no investigation two and half years after the shelf life of the drug was over in Jan 2016.
2. Explanation by Cipla dated 26.03.2018 **[Pages 467, 469, 470 of CIPLA EVIDENCE DOCUMENTS] [sent separately] [It will take around 6-7 minutes to open this file]** was sent to Drugs Controller General of India and copy forwarded to me, the complainant and aggrieved party.
3. Upon noticing that the explanation was full of lies by Cipla Global Head Pharmacovigilance, I wrote to the Director of FDA Goa on 21/04/2018 **[Exhibit**

FDAGOAPAGE9-10 of FDA GOA EVIDENCE DOCS].
I told her that the matter was far too serious than mere death of my wife. Lives of citizens of India are valuable and cannot be used as guinea pigs to conduct trials by doctors and pharma companies. That I had not made allegations against Cipla drug Rokfos but asked Cipla to conduct an investigation so that I could pursue my case against the doctors for deliberately not taking action on the serious adverse reactions of IV Rokfos and watching my wife sinking to her death.

I had asked FDA Goa Director to ask Cipla to respond point by point to my allegations so that the matter was clear. That I can put forward their explanation in the criminal case against the doctors as well as Cipla.

4. Further on 01/05/2018, I wrote to FDA Goa Director on false, baseless and defamatory information on the health condition of my wife prior to administration of drug Rokfos **[Exhibit FDAGOAPAGE11-15 of FDA GOA EVIDENCE DOCS]**.
5. I also wrote to all the Directors on Board of Cipla on 9th May 2018 demanding an unconditional apology **[Pages 92-94 of CIPLA DRUG TRIAL] [Attached].**
6. FDA Goa Director forwarded my letter addressed to her to Cipla Limited on 15/05/2018 **[Exhibit FDAGOAPAGE16 of FDA GOA EVIDENCE DOCS**]. She asked Cipla for necessary action at their end.
7. DCGI wrote to FDA Goa Director asking for final decision in the matter.
8. FDA Goa Director responded to DCGI on 15/05/2018 **[Exhibit FDAGOAPAGE17 of FDA GOA EVIDENCE DOCS**] stating that the Directorate had received the complaint on 01/01/2018 via e-mail. The said complaint was investigated by Investigating Officer of their Directorate on visiting the premises and was reported that as per Cipla's policy, all complaints related to adverse drug reaction are investigated at Drug Safety Department of Cipla at Mumbai and subsequent follow up reports are submitted to Drugs Controller General (India) as per pharmacovigilance guidelines and the said adverse drug reaction case was not reported to their Directorate. Further firm was served with show cause notice and was personally heard in the matter. As it is a serious adverse drug reaction case copy of complaint and submission from Cipla along with reply from complainant on explanation submitted by Cipla was forwarded for information and necessary action at DCGI end.
9. Suddenly out of the blue in May 2019 (exactly one year after letter dated 15/05/2018 to DCGI), FDA Goa Director sends letter to Cipla **[Exhibit FDAGOAPAGE18 of FDA GOA EVIDENCE DOCS**]. It was stated that explanation submitted by Cipla was **not satisfactory** as they had failed to intimate the Directorate regarding serious Adverse Drug Reaction as required under Para (2) of Para 28 Schedule 'M' of Drugs and Cosmetics Rules. However, considering the assurance given by Cipla that such violation will not be repeated and that on investigating the matter by the Investigating Officer of the Directorate, no adverse findings were reported in respect of quality of quality of the product. That no action is taken against Cipla. However, they were warned that if such lapses were reported in future strict action as per provision of law will be taken against Cipla.
10. FDA Goa Director was aware of strict action as per provision of law. Was this a once off waiver of the law given by FDA Goa Director to Cipla? What was the cost to Cipla and what was the benefit to FDA Goa Director in this waiver of the law? And what was the cost to the aggrieved? Whose life is it anyway? Would

FDA Goa Director act in a similar manner if anyone from her family was the casualty from sub-standard drug causing death.

11. FDA Goa Director was least concerned of life lost whereas was full of empathy towards the drug killer, Cipla. Was this not open corruption?
12. What about Cipla not investigating as per statutory guidelines; Schedule 'M'. How did Investigation Officer arrive at his 'Verbal Clean Chit'. Both FDA Director and Investigating Officer are answerable for abetment to 'Crimes against humanity'. Colluding with criminals is an anti-national act and amounts to sedition. In this case it is all the more serious as lives of millions are at stake. Both FDA Director and I/O should be suspended forthwith and investigated by the Anti-corruption Bureau as well as by the CBI.
13. FDA Goa Director did not bother to respond to me asking for point by point answers from Cipla.
14. FDA Goa Director should be aware of Schedule 'M' provisions as described under point **1 a)** above.
15. Food and Drugs Administration is a law enforcement agency to ensure safe drugs of good quality and purity to the residents of the state. Not to protect the criminal offenders.
16. **[Exhibit FDAGOAPAGE19 of FDA GOA EVIDENCE DOCS]** is letter dated 15/05/2019 to me stating that there were no lapses on the part of the firm as regards quality of the drug batch in question. However, the firm had failed to intimate this Directorate regards the serious adverse event.
17. This was followed by letter from office of DCGI dated 23/05/2019 **[Exhibit FDAGOAPAGE20 of FDA GOA EVIDENCE DOCS]. That the matter was under examination and active consideration with DCGI and FDA Goa.** Since one year, the matter was under active consideration with DCGI office. Consideration for what? Settlement? They repeatedly asked IPC secretary cum scientific Director for his opinion hinting at compensation. Also asked my feedback on resolution of the grievance. I had responded but there was no reply from the DCGI. Clear admission of foul play by Cipla. Can DCGI act as intermediary in a homicide case? DCGI has to respond else face the law.
18. Both DCGI and FDA Goa Director in collusion tried to hoodwink a senior citizen seeking justice in death of his wife sacrificed as a guinea pig in a drug trial. Manipulations to dates are evident in both FDA Goa and DCGI letters to me mentioned above.
19. After FDA Goa Director's attempt to force a senior citizen to abort seeking justice and at the same time exonerate criminal Cipla, I had asked FDA **Goa Director vide letter dated 12th June 2019 to respond to her letters to Cipla as well as the aggrieved party. [Exhibit FDAGOAPAGE21-26 of FDA GOA EVIDENCE DOCS]**.
20. Subsequently vide letter dated 29th June 2019, I had written to FDA Goa Director attaching full details of my analysis of each and every point raised by Cipla in their explanation to me and FDA Goa Director **[Exhibit FDAGOAPAGE27 of FDA GOA EVIDENCE DOCS]**.
21. The letters by FDA Goa Director points to open collusion with pharma company Cipla.
22. Corruption with criminal offenders **(foreign promoters)** playing with lives of **citizens of 'Bharat Mata'** are anti-national seditious acts which will doom the heath of the nation. Future students of Chemistry and Medicine will be doomed
23. Not only Indians; Cipla has around 55 subsidiaries across the world. Lives of millions are at stake.

24. Attached is **"Cipla Drug Trial" i**n the form of a book running into 29 chapters. It has been proved with conclusive evidence that there is a massive cover up to try and save Cipla from provisions of the law.
25. Cipla reported the serious ADRs of drug Rokfos which caused death of my wife to IPC five years after taking the aggrieved for a ride and after 'Clinical Trial' in nexus with doctors **[Exhibit FDAGOAPAGE28-30** of FDA GOA EVIDENCE DOCS]. This itself is proof of **"FOUL PLAY"** involved.
26. There was no need to hide known side effects of a drug unless foul play was involved in manufacture and trial conducted on a vulnerable innocent patient.
27. Attached please find order by the **Maharashtra State Consumer Forum** indicting and holding doctors and hospitals "Guilty" causing death of my wife from drug Rokfos.
28. Attached, please find **Charges framed by Maharashtra Medical Council** against both owner doctors of Maruti Nursing Home. That treating doctor failed to treat the patient after complications of drug Rokfos.
29. Attached, please find **US FDA detailed warning letter to Cipla** Limited for twelve serious violations of Good Manufacturing Practices at their Goa facility. Drug that killed my wife was manufactured at Cipla Goa facility.
30. Attached, please find **Cabinet Secretariat Order** asking for action by the Health Secretary. This was from the Cabinet Secretary and his team of around six to seven deputies. They took time to go through my book and evidences given which in itself is proof of gravity of the matter and being of concern to the nation.
31. Attached, please find **Questionnaire to Cipla.** Cipla could not answer the questionnaire when senior editors questioned them. Later silenced the journalists with their money power. I have e-mails and WhatsApp Chats with the journalists and senior editors of leading newspapers.
32. Directorate of FDA Goa is bringing disrepute to the State of Goa. That pharma companies manufacturing in the state of Goa need not fear Drugs and Cosmetics Act, 1940 and Rules thereof. Regulators will let them off with a warning.
33. They are destroying the vision of the hon'ble PM, Shri Narendra Modiji that "Consumer Protection is a must for the creation of "New India". "Nexus between pharma companies and doctors be broken"
34. **Corrupt regulators** will also be detrimental to India's interests of **"Make in India" and "AtmaNirbharBharat".**

I request the hon'ble Chief Minister of Goa to appoint a SIT under a sitting Judge of the High Court to investigate FDA Goa officials especially FDA Goa Director and Investigation Inspectors who gave a verbal clean chit without investigation and documentation required as per Schedule 'M' of Drugs and Cosmetics Rules.

Not only this matter should be investigated but also the functioning of the Directorate. There seems to be serious corruption involved between FDA Goa officials and drug manufacturing companies in Goa.

After all, it is the PM's vision for a **"New India"** which inspired me and spurred me to investigate **"Drugs for Profit" and "Cipla Drug Trial"** so that I could play a role in the commitment of our beloved PM to the health and prosperity of our nation. It has taken me six years to unearth this horrific racket of Pharma-doctor nexus which will ultimately destroy the health of a young India. I spent all of my time for six and half

years in spite of my and my daughter's lives being destroyed by Cipla in nexus with doctors. The criminals are roaming free till this date.

PMJAY is the beginning. Major steps are on the way by National Health Authority for **"Ayushman Bharat".**

Whatever the compulsions and pressure by the Pharma lobby, **"Consumer will finally win"** as the Heart of Shri Narendra Modiji is with the Consumer. Live example of "Cipla Drug Trial" is before the world. There is Pin Drop Silence by Cipla Board of Directors. This is open acceptance of **"Guilt".**

In an official communique, DoP has warned all pharmaceutical organizations and associations including OPPI, IPA, IDMA, BDMA, etc. to fall in line. The hon'ble PM has repeatedly warned as early as in year 2020 that he is constrained to bring a strict law. **And why not ?**

Pharma Industry need not fear laws enacted by the Parliament if they adhere to the laws of the land. It is only the corrupt and criminal mafia in the pharma and medical industry who are bringing disrepute to their respective professions. Why should IMA and OPPI not discard the black sheep in their family? rather than face embarrassment before the citizens of the country? I am not Anti-pharma. Loved Life Science before a drug destroyed our lives.

Thanking you for your co-operation,
Sincerely yours,
Umeshchandra Barkur

A-15, Neeta Apartments, Chaphekar Bandhu Marg, Mulund East, Mumbai 400081.
Cell : 98201 17923