Date : 12th June 2019

To :

Director, Directorate of Food and Drugs Administration, Government of Goa.

**Subject :** Adverse Drug Reaction of Rokfos – 1) Your letter dated 21st March 2019 to Cipla Ltd and 2) Your letter dated 15th May 2019 to the undersigned.

Ms Jyoti Sardesai,

I am seeking information on the following points in your letters mentioned above.

1. Investigation by the Inspecting Officers of your Directorate.

   ***Can you send me copies of reports by the Inspecting Officers of your Directorate ?***

2. Investigating matter by the Inspecting Officer of this Directorate - no adverse findings were reported in respect of quality of product and no action was taken.

   ***What was the basis of arriving at "no adverse findings in respect of product quality" ? Why no action ?***

3. Strict action as per provision of law will be taken in future.

   ***What are the provisions of the law ?***

4. There are no lapses on the part of firm as regards quality of the drug batch in question.

   ***What is the basis of the Inspecting officers conclusion that there were no lapses on the part of the firm as regards quality of the drug batch in question ? The ADRs occurred in June 2014. Cipla is on record that they had reported to DCGI, PVPI and FDA-Goa. letter from your Directorate itself says that the ADRs were not reported. The batch was manufactured in February 2014. Inspite of repeated appeals by the aggrieved party, Cipla deliberately suppressed information on the ADRs which is proof enough of FOUL PLAY. Shelf life was over in January 2016. What was the modus operandi of finding that there were no lapses by the Inspecting Officers ?***

5. Firm had failed to intimate this Directorate regards the serious adverse event.

*DGHS information to me on the protocol to be followed (Schedule M of Drugs and Cosmetics Rules 1945) should have been followed by the Inspecting Officers of your Directorate. Did the Inspecting Officers record the complaint and actions taken by Cipla ?*

- *As per Schedule M of Drugs and Cosmetics Rules, all complaints thereof concerning 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 drug reactions resulting from the use of a drug along with comments and documents shall be forthwith reported to the concerned licensing authority.*

  *A prompt and effective product recall system of defective products shall be devised for timely information of all concerned stockists, wholesalers, suppliers up to the retail level within the shortest period.*

  *The recalled products shall be stored separately in a secured segregated area pending final decision on them.*

6. Warning issued for failing to intimate this Directorate regarding serious Adverse drug reaction as per requirement of Drugs and Cosmetics Rules 1945.

*This is a homicide case of drug causing a death suppressed by doctors of three hospitals, FDA-Maharashtra officials and by the main offender Cipla limited. Can International drug companies get away with only a warning ? And the consumer, the common man left to grieve ? FDA is the primary agency for providing safe medicines with good quality and purity. Drug causing death will be let off with a warning ?*

7. Explanation submitted by Cipla is not satisfactory.

*The explanation submitted by Cipla was not only "Not Satisfactory" but full of "BLATANT FALSEHOOD". This is a homicide case. Explanation on "Clinical trial induced adverse drug reactions" cannot be dismissed by FDA-Goa*

***Director by merely saying "Not Satisfactory". Rather Cipla should have been prosecuted by now for deceiving FDA authorities with false chemical/medical theories just to prove that Rokfos was not the cause of death.***

8. Assurance given that such violation will not be repeated.

***Can drug manufacturing companies produce sub-standard drug and upon the drug causing death suppress the ADRs, do not recall the sub-standard drugs, violate the laws (schedule M), deceive the consumer, deceive the FDA authorities ?***

***FDA authorities will let them off with a warning ?***

***This is collusion with sub-standard drug manufacturer and the officials should be charged with abetment and acting as accessories to this horrific crime.***

9. There was complete cover up of the adverse drug reactions. Drug control authorities as well as FDA authorities (both Maharashtra and Goa) have ensured protection to drug manufacturer Cipla Limited in spite of the voluminous evidence of malpractices and criminal offences gathered against Cipla.

10. In spite of drugs sold illegally and ORDER by the Maharashtra State Commission which indicts the doctors for faulty treatment with Cipla drug Rokfos causing death, there is no action by the Commissioner of FDA-Maharashtra against the doctors.

11. **This network is very dangerous (Drug companies + Doctors + Hospitals + FDA authorities of the States).** This has been reproduced before the Executive Director Finance in PMO (Ayushman Bharat PMJAY) as well as the Health Minister, Dr.Harsh Vardhan.

12. Action should be initiated against Cipla Chairman Dr.Yusuf Hamied for hoodwinking the citizens and the world with his false public claims. This is "Professional Misconduct" at the highest level.

13. FDA officials involved in coverup of the criminal offences should also be booked for abetment to this crime along with the Accused.

14. **Complicity by Directorate, FDA, Government of Goa :**

a) One year after Cipla's false explanation was conveyed by me with complete evidence to Directorate of Food and Drugs Administration, Govt. of Goa, the directorate is now trying to dilute serious criminal charges against Cipla of producing sub-standard drug Rokfos which caused a death.

b) Suddenly, out of the blue and one year after Cipla's false explanation, the Director of DFDA-Goa chooses to send these letters to Cipla and the complainant. This is a clear case of trying to support the killer drug manufacturer.

c) There was no mention of Rokfos being of "standard quality" for five years since August 2014 till May 2019 by the rank and file of Cipla including Product Manager, Cipla Drugs Safety as well as the Global CEO and M.D.

d) There was no mention of Rokfos being of "standard quality" since January 2018 till May 2019 by the Director, Directorate of FDA-Goa.

e) Cipla cannot plead **"Ignorance of the Law"** in relation to Schedule 'M'. These are standard procedures to be followed mandatorily.

- An international drug company not following the laws of the land only proves FOUL PLAY involved in manufacturing sub-standard drug Rokfos. Besides, this drug was being administered as a "Clinical Trial" which has been admitted by none other than the treating doctor as well as by the doctor involved in illegal sale of Rokfos to other hospitals/doctors.

f) As per letter from the Director of FDA-Goa to the DCG(I) dated 15th May 2018, the Director did not want to take action after the false explanation was informed to her by me. She put the onus on DCGI to take action. Why were these two letters produced all of a sudden in March and May 2019 ?

15. **Charges against Cipla and Punishment**

a) Violation of Drugs and Cosmetics Act, 1940 and Drugs and Cosmetics Rules.

b) Manufacture of sub-standard drug 'Rokfos' causing unnatural and untimely death of an innocent.

c) Nexus with doctors/hospitals - **'Clinical Trials'** on unsuspecting patients. This is **a serious anti-national activity against the people of the country.**

d) The doctors of the private hospital (Maruti Nursing Home, Mulund, Mumbai) were selling Cipla sub-standard drug Rokfos 'illegally' to other hospitals/doctors.

e) The doctors were given incentive of Rs.745/- to sell drug Rokfos for minor bone problems as clinical trials. Purchase price was Rs.2,205/- and MRP was Rs.2,950/-. It was sold to the patient for Rs.3,500/-

f) Cipla Limited suppressed the ADRs even after being informed by the treating doctor. Cipla did not recall the drugs.

**g)** Fine would have been huge – Penalty under section 27 of Drugs and Cosmetics Act, 1940- three times the value of drugs confiscated **(Page 184).**

h) Cipla Global Head Pharmacovigilance deceived the Director of FDA-Goa with imaginary and false medical/chemical theories just to prove that Rokfos was not the cause of her death.

i) Cipla pharmacovigilance head created an imaginary 'Thesis' on the health condition of the patient prior to Rokfos being administered to her.

j) Cipla Management stooped to very low morals by false, derogatory, defamatory and disgusting remarks on the health condition of the patient prior to Rokfos being administered to her. **It was like rubbing salt to injury.**

k) Cipla protected the treating doctors on their faulty treatment with false explanation to FDA-Goa Director.

**l)** Cipla took the aggrieved party (consumer) for a ride with false statements that they had reported the ADRs immediately to three topmost drug control authorities – FDA-Goa, DCGI and PVPI.

**m)** Penalty under Section 27 of Drugs and Cosmetics Act, 1940 – Penalty for manufacture, sale, etc., of drugs in contravention of this chapter.

Punishable with imprisonment for a term which shall not be less than ten years but which may extend to imprisonment for life for persons responsible for manufacture and sale of the sub-standard drug Rokfos.

Also liable to fine which shall not be less than ten lakh rupees or three times the value of the drugs confiscated, whichever is more.

Draft Pharma Policy has rightly proposed **a marketing ban of one year, confiscation of the top most selling brands and hefty fines.** This should be enforced upon by CDSCO against Cipla Limited for the serious multiple criminal offences under Drugs and Cosmetics Act, 1940, violation of Drugs and Cosmetics Rules, multiple malpractices and Professional Misconduct.

n) Sole objective was to amass money through illegal means. Cipla played with the lives of the citizens of India. The entire batch of Rokfos manufactured has to be considered to arrive at fine.

o) Cipla Head Pharmacovigilance deceiving FDA-Goa Director with false medical/chemical theories should be construed as **anti-national activity** - deceiving the scientists of the country, deceiving the doctors, medical profession and students of Chemistry and Science.

Hoping to get a satisfactory and meaningful reply at the earliest.

Umeshchandra Chandu Barkur

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Cc : Drugs Controller General of India.

Cc : Commissioner, FDA-Maharashtra.

Cc : Management – Cipla Limited.