Date : 27th October 2021

To :

The Hon'ble Lokayukta of Maharashtra,

Justice Shri V.M.Kanade

Subject : Complaint No. 4156 dated 31/10/2019

Response to Joint Investigation Report

1. Joint Investigation was organised by Drugs Controller General (India) HQ.
2. Summarised observations (19 points) & Remarks (4 points) are explained by me below, which will reveal that this was a bogus investigation organised by DCG(I) and bogus report by the following :
   a) Drug Inspector, FDA Maharashtra, Greater Mumbai, Zone-4.
   b) Drug Inspector, CDSCO WZ, Mumbai.
   c) Professor and HOD, Municipal Medical College & General Hospital, Mumbai (Expert).
3. Joint Investigation by CDSCO and FDA was a Fraud and an unpardonable SIN committed on the citizens of the country which has exposed :

   "Nexus with criminal pharma" "Nexus with unethical doctors"

   Fully supported by Drug Controllers under

   CDSCO

   (Central Drugs Standards Control Organisation)

   "Freedom to manufacture sub-standard drugs" and

   "Prescription for Trials"

   This could be the norm prevailing in the entire country and citizens are paying the price for corruption by Public Servants.
4. Report was sent to CDSCO Enforcement Division under DCG(I).
   - Nothing was enforced by CDSCO/DCG(I).
   - Nothing was enforced by FDA Maharashtra.
5. The only objective of this conspiracy and deplorable act by FDA and CDSCO was to issue a letter to Cipla Limited that no action is taken against them.
   - ***Note :*** *This was after Cipla's false explanations to FDA Goa Director was exposed by me and I had asked FDA Maharashtra Joint Commissioner to take action.*
   - *Cipla Limited Directors should have been prosecuted in May 2018.*

- *Letter of Pardon was issued by FDA Goa Director who had no role in this investigation.*

6. *This letter was issued upon an assurance given by Cipla Limited that such lapses will not occur again.*
   - *FDA Goa Director called deaths as lapses.*
   - *No value for lives of citizens.*
7. Joint investigation was conducted on 02nd February, 2019.
   a) A year later, letter to complainant by Shri Hemant Mahajan, Under Secretary, Government of Maharashtra, Department of Medical Education and Drugs (D.M.E.R.) along with Joint Investigation Report was kept ready, dated 11.02.2020.

      This was exactly one month prior to the first hearing on 12.03.2020 by the erstwhile Hon'ble Lokayukta, Justice Shri M.L. Tahaliyani.
      - Report was not submitted on 12th March 2020 during the hearing.

   b) The Report was sent to the complainant a year later, vide speed post dated 16.02.2021.

   c) This came after authorities viz. Directorate of Health Services, Deans and expert committee doctors were exposed before the Hon'ble Upa-Lokayukta of Maharashtra, Shri Sanjay Bhatia for destroying expert committee report and attempt to tamper with charges framed by Maharashtra Medical Council had failed.
8. Three months prior to the Joint investigation, Maharashtra State Commission (Consumer Court) had already held doctors & hospitals guilty and asked to pay compensation amounting to 19,57,554/- towards losses incurred (medical bills, etc.) Execution Order was shown to the complainant and advocates of all the guilty parties.
9. Order of State Commission and Medical Council are identical.

   That drug Rokfos was administered Ad Hoc without ascertaining indications of use and without blood investigations of the patient. Treatment was not as per severity of disease. Even after adverse reaction, treating doctor failed to take care of the patient. Proper documentation was not maintained and In-patient records were manipulated. Drugs were sold illegally without a valid licence.
10. **Joint Investigation Report of** M/s Maruti Nursing Home **(Pages 1 to 9) :**

Subject – Joint investigation of M/s Maruti Nursing Home, Mulund, Mumbai in connection with complaint regarding death of Smt.Kamini Barkur w/o Sh. Umeshchandra Barkur by sub-standard drug Rokfos, manufactured by M/s Cipla Limited and sold illegally at Maruti Nursing Home, Mulund.

***Note – Response by Complainant** : Death was from sub-standard drug, but drug manufacturer was not part of the investigation even after his explanations to FDA Goa Director were proved as blatantly false.*

Documents verified

Investigation officers verified the in-patient record file of Late Smt. Kamini Barkur available at M/s Maruti Nursing Home, Mulund and pathological test reports from 09.06.2014 to 14.06.2014. Investigation team also collected documents from FDA Maharashtra, Bandra office w.r.t. inspections performed and action taken by FDA Maharashtra in the subject matter.

***Note – Response by Complainant** :*

- *The investigators and especially expert Professor must have perused the pathological reports and discovered that Pancytopenia (drop in all three blood counts) occurred on 12th June 2014. WBC fell from 20,080 to 2,300 and platelets from 143,000 to 95,000 in a single day.*
- *It was a dire emergency. The doctors watched the patient sinking to her death for three days at a stretch.*
- *They sent her in a panic on 14th June 2014 i.e. two days prior to scheduled surgery for cord compression (cause of stiff neck) to Platinum Hospitals. Surgery was fixed on 16th June 2014.*
- *Pancytopenia was not informed to Platinum Hospitals even by Spine surgeon, Dr.Satyen Mehta under whose consultancy the patient was admitted.*
- *There were no inspections done by FDA Maharashtra in spite of repeated requests and appeals by the complainant.*
- *The only inspection and investigation required as per Statutory guidelines was to send a sample from the concerned batch to Govt Analyst in Mumbai to determine Standard Quality.*

COMPLAINT

a) *My complaint dated 28th April 2015 was death of my wife and drugs sold above MRP along with Complaint to Cipla Limited dated 16.08.2014, giving batch number, manufacturing date, expiry date, etc.*

- *Both criminal offender, Cipla Limited as well as law enforcement agency, FDA Maharashtra did not follow statutory guidelines; Violated Schedule 'M' of Drugs and Cosmetics Rules.*
- *Assistant Commissioner (Zone 4) with whom my complaint was lodged was subsequently arrested by ACB in FDA Bandra office itself. This media report has been submitted to Office of Lokayukta.*

b) *I met Joint Commissioner, Shri O.Sadhwani along with Dr.Metekar of FDA, Mumbai. Dr.Metekar told me that "Purchase was illegal" and "Sale was illegal". There could be no defence that the drug was of standard quality.*

- *However, Mr.Sadhwani said that the drug causing death had to be proved in Consumer Court.*
- *Regarding my name not being included in Mazgaon Court Complaint, he replied; "If they beat you up?"*

Summarised observations

Point 1. Provisional diagnosis - Cervical spondylitis & stiff neck.

Note – Response by Complainant :

- *Cause of stiff neck had to be diagnosed and MRI was the first line of action.*
- *Without diagnosis, treatment could not be started. Only pain-killers to relieve the pain.*
- *Instead, cancer injection, Rokfos was administered to cure stiff neck in a single day.*

Point 2. Complainant in written complaint dated 23/07/2018 made to DDC(I) WZ , Mumbai has submitted photograph of carton of drug Rokfos produced by treating doctor in patient record of his wife.

As per available information on carton, expiry date of drug was **Jan.16** and drug was administered to Smt.Kamini Barkur on 09/06/2014.

Note – Response by Complainant :

- *Written complaint was by complainant but report was suppressed from the complainant.*
- *This is similar to Dean and doctors suppressing "Expert Committee Report".*

Point 3. On prescription dated 09/06/2014 single dose of drug Zoledronic acid IV (Zobone IV) was prescribed to Smt.Kamini Barkur. Dr.Mihirgiri Goswami stated that single dose of Zoledronic acid IV (Rokfos IV) was administered to her on 09/06/2014.

Note – Response by Complainant :

- *There were no allegations of double dose given.*
- *The investigation team is supporting cancer drug given for stiff neck.*

Point 4. M/s Maruti Nursing Home, has submitted purchase invoice No.00788 dated 25/04/2014 received from AMI Agency, Shop No.2, Pavwala Chawl, Ganesh Maidan, Sainath Nagar, Ghatkopar (W), Mumbai-26 for purchase of drug ROKFOS IV, Batch No.V40056, Quantity Purchased -5 units.

Note – Response by Complainant :

- *Raid was conducted at Maruti Nursing Home in July 2015. The remaining 4 units purchased were not in stock. Neither were sale invoices produced. Medical records have to be preserved for three years as per Regulations by Medical Council of India. The remaining 4 units were destroyed as they were sub-standard and hence not investigated by Cipla Limited.*

Point 5. As per available records with hospital i.e. patient file, it was observed that only single dose of drug Zoledronic acid, IV was administered to Smt.Kamini Barkur on 09/06/2014 and said drug was not administered to her again during her hospitalisation at M/s Maruti Nursing Home till 14/06/2014.

Note – Response by Complainant :

- *No need to repeat this again and again. There were no allegations of double dose.*
- *What was the objective? That one dose of this cancer injection was okay to have been administered to cure stiff neck in a single day.*
- *Stiff neck is not in indications of use sent by **DGHS** and is submitted to office of Lokayukta.*

Point 6. As per available records, Smt. Kamini Barkur was discharged from M/s Maruti Nursing Home on 14/06/14. It was explained by Dr.Mihirgiri Goswami that she was shifted to Platinum Hospital, G-103, D.D.Upadhyay Marg, Mulund for further treatment.

Note – Response by Complainant :

- *Patient was shifted in a panic and in a very critical condition for "Surgery only" as per Discharge Card "Shift to Plat for Surgery". "Plat" meaning Platinum Hospitals.*
- *It is interesting to note that "Plat" was manipulated as "Platelets" in second set of in-patient records given by Dr.Mihirgiri Goswani of Maruti Nursing Home.*
- *No transfer summary was given. Transfer summary should state the brief medical history, results of tests conducted and actual condition of the patient at that moment of time before transferring the patient.*
- *Within one hour of admission to Platinum Hospitals, she was shifted to Intensive Care Unit (ICU).*

Point 7. Complainant made complaint dated 28th April 2015 to Joint Commissioner, FDA Maharashtra that drugs were sold above MRP at M/s Maruti Nursing Home.

Note – Response by Complainant *:*

- *My complaint stated that, my wife after being admitted for six days at Maruti Nursing Home was shifted in a critical condition and later succumbed to her death.*
- *I had also given my complaint dated 16th August 2014 addressed to Cipla Limited to investigate death of my wife, reason being drug-induced. I had attached photocopy of purchase invoice and carton of drug Rokfos, giving all details.*

RTI - FALSE, EVASIVE MISLEADING REPLIES

False, misleading, evasive replies by FDA Maharashtra to RTI queries.

- *Rokfos is manufactured in Goa. Hence they have no jurisdiction.*

  Note – Response by Complainant *:*

  Whom will residents of Mumbai go to?

- *There is no record of sub-standard drug.*

  Note – Response by Complainant *:*

  My complaint was to investigate whether the drug was of standard quality. That was the Statutory guideline violated by both criminal offender Cipla Limited as well as Law Enforcement Agency, FDA Maharashtra.

- *Drug Inspector has launched prosecution in Mazgaon Court.*

Note – Response by Complainant :

Drug Inspector of FDA Maharashtra has himself filed the complaint at Mazgaon Court, has not followed up on his complaint for six years and has signed on Joint Investigation Report saying that matter is Sub-Judice.

Point 8. In view of complaint dated 28th April 2015 made by Shri Umeshchandra Barkur, officials from FDA Maharashtra raided the premises of M/s Maruti Nursing Home on 22/07/2015 along with two witnesses. It was observed that hospital is involved in sale of drugs without holding requisite licence as per the provisions of Drugs and Cosmetics Act, 1940.

Note – Response by Complainant :

- *My complaint was not regarding drugs being sold illegally. How could I know that they did not have valid licence?*
- *My complaint was manipulated as a complaint received from a confidential source.*
- *My name was not mentioned in the complaint.*
- *Nothing about drugs sold above MRP and nothing about death of my wife.*
- *Nothing regarding Adverse Drug Reactions.*

Point 9. Drugs Inspector, FDA Maharashtra, has filed a case against Dr.Mihirgiri I. Goswami, Proprietor M/s Maruti Nursing Home, Shop No.1 & First Floor, Girnar Society, Hanuman Chowk, Gokhale Road, Mulund (East), Mumbai 400081 and Smt. Ashwini Kallapa Kamble Receptionist cum salesman at M/s Maruti Nursing Home, Shop No.1 & 1st Floor, Girnar Society, Hanuman Chowk, Gokhale Road, Mulund (East), Mumbai 400081 in the Court of Hon'ble Metropolitan Magistrate's 15th, Mazgaon Court, at Sewree, Mumbai for contravention of section 18(c), Section 18-A and Section 22(1) (cca) of Drugs and Cosmetics Act., 1940.

Note – Response by Complainant :

- *Till date, there has been no follow up on the case for six years.*
- *Evidence before charges has not been submitted.*
- *It was illegal sale of drugs for unethical monetary rewards and prescription for trials.*
- *Sale invoices had to be produced.*
- *There were 5 units purchased. Sale invoices for remaining 4 injections*

had to be produced.

Point 10. Said case is under court of law and matter is sub-judice.

Note – Response by Complainant :

- *Drug Inspector of FDA Maharashtra has himself filed the complaint at Mazgaon Court, has not followed up on his complaint for six years and has signed on Joint Investigation Report saying that matter is Sub-Judice.*
- *Mockery of the Legal System.*

Point 11. Complainant made complaint dated 14th May 2018 to Joint Commissioner FDA, Greater Mumbai Division, Maharashtra w.r.t. death of his wife from serious adverse drug reactions of injection IV Rokfos manufactured by Cipla Ltd.

Note – Response by Complainant :

- *My complaint originated in 2014 and not in 2018.*

a) *My complaint dated 14th May 2018 with FDA Maharashtra Joint Commissioner was after Cipla Head Global Pharmacovigilance was exposed for deceiving FDA Goa Director with 'Fake imaginary diseases' and 'Fake imaginary treatment' for the same.*

I had enclosed 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 injection IV Rokfos being administered to her and which caused her death.

I had told the Joint Commissioner of FDA Maharashtra that this was a reminder to him asking for actions taken by FDA Maharashtra, Mumbai against ***A.*** *Maruti Nursing Home* ***B.*** *Cipla Limited and* ***C.*** *FDA Maharashtra Mumbai officials.*

- *That actions were requested by* ***A.*** *DCG(I)* ***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.*

- ***Note :*** *Instead of actions against the accused viz Cipla Limited, FDA Maharashtra, Mumbai officials sent one sample of injection Rokfos to government laboratory and declared Rokfos as being of standard quality. This was four years after death of my wife in 2014.*

b) *Both Cipla as well as FDA Maharashtra officials did not send a sample in 2014 even after repeated requests by the aggrieved to investigate their drug causing such serious ADRs never seen before with Zoledronic Acid.*

- *They were aware that the batch would fail 'Standard Quality' test as it was specially manufactured for trials on vulnerable, innocent patients.*

c) *Test report of this sample sent in 2018 was given to the Joint Investigation Team (Specially formed to absolve both injection Rokfos as well as 'Unauthorized Trial' conducted by Maruti Nursing Home doctors in nexus with Cipla Limited). This was given to them in* ***January/February 2019.***

d) *The Joint Investigation Report was sent by DDC(I) WZ, Mumbai to the Drugs Controller General (India) CDSCO (HQ) dated* ***20th March 2019.*** *Initially it was dated* ***15th March 2019.***

e) *The Joint Investigation Team did not bother to check for any details with drug manufacturer Cipla Limited on the serious ADRs and whether they had investigated the drug. As per Cipla Authorized Representative, treating doctor, Dr.Mihirgiri Goswami had informed them of the serious ADRs on 6th August 2014.*

f) *The Joint Investigation Team did not bother to check indications of use of injection IV Rokfos sent to Maruti Nursing Home and which was very much there in Complaint file before the State Commission.*

g) *FDA Goa Director issued a clean chit dated* ***21st March 2019 to Cipla (Correction to date is visible and obvious).*** *This was the very next day after Joint Investigation Report.*

- *That in spite of their explanation not being satisfactory and in spite of failure to report the serious ADRs, no action was taken against Cipla.*

- *That in future strict action as per provisions of the law will be taken against Cipla.*

Note – Response by Complainant :

- *What about life lost ?*
- *Only warning, even after death was caused?*
- *Only warning, even after explanation was not satisfactory?*
- *Only warning, even after failing to report the serious ADRs?*
- *Investigating Officer was investigating the accused and how did he get satisfied with explanation of the accused criminal offender?*
- *Any documents to substantiate Cipla's claims?*
- *How could you determine lapses in quality of manufacturing four years after the death? and two years after the shelf life of the concerned batch in question was over in January 2016.*
- *Clean Chit W/O investigation?*
- *What about investigation as per Schedule 'M' of Drugs and Cosmetics Rules? What about innocent sacrificed?*
- *FDA Goa Director did not deem it fit to question why the drug was not investigated and why statutory guidelines were not followed.*
- *FDA Goa Director told the killer drug manufacturer that "If you kill again, strict action will be taken as per provision of the law".*
- *Drugs and Cosmetics Act, 1940 was in place and was applicable to all the States of India, including Goa.*
- *Why was this law deferred by the Director, Directorate of Food and Drugs Administration, Government of Goa to an unscrupulous pharma company playing with lives of citizens of India.*
- *What if a loved one of FDA Goa Director was the casualty?*
- *Would the killer still be pardoned till he commits a homicide again in the future?*
- *The farce of Joint Investigation Report has been dealt with exhaustively in my criminal writ Complaint and facts of the matter before the Supreme Court of India.*

Point 12. To investigate the subject matter, officials from FDA Maharashtra, visited premises of Novacare Drugs Specialities Pvt. Ltd. 14 & 15, Vardhman

Complex, L.B.S. Marg, Fitwell Compound, Vikhroli (W), Mumbai 400083 on 24/05/2018.

Point 13. Stock of drug Rokfos Injection IV B.No. 40056 was not found on premises of M/s Novacare Drugs Specialities Pvt. Ltd. Vardhman Complex, L.B.S. Marg, Fitwell Compound, Vikhroli (W), Mumbai 400083

However, stock of following batches of Rokfos injection IV were found in the premises of M/s Novacare Drugs Specialities Pvt.Ltd. Out of two batches drugs inspector, FDA Maharashtra had taken sample of Batch No. G170312 under Form 17 Dated 24/05/2018 for the purpose of test and analysis.

Note – Response by Complainant *:*

- *There was no point in sending sample of a drug batch, four years after death of my wife and two and half years after shelf life of the batch in question was over.*
- *They did not send a sample when the complaint was made in 2015.*
- *Cipla did not send a sample in 2014 in spite of repeated reminders by the aggrieved.*
- *Both Cipla and FDA Maharashtra violated Statutory Guidelines; Schedule M of Drugs and Cosmetics Rules 1945.*
- *DGHS sent me Protocol to be followed by drug manufacturing companies in case of serious ADRs reproduced below:*

  "As per Sch M of D & C Rules, 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 drug reactions resulting from the use of a drug along with comments and documents shall be forthwith reported to the concerned licensing authority".

Point 14. The said drug sample was sent to the Government Analyst, Food and Drugs Control, Laboratory, Mumbai, Maharashtra along with Form 18 dated 24/05/2018 for analysis including test for Toxicity.

Point 15. The sampled drug was declared as of Standard Quality vide Govt. Analyst, Drugs Control Laboratory vide report No. STD/MUM/106142/2018 dated 12/09/2018. Drug sample was also found meeting test for toxicity.

Note – Response by Complainant :

- *There was no meaning to, sending a sample in 2018.*
- *What was required was to question Cipla regarding false explanations on the health condition of the patient prior to drug Rokfos being manufactured and which caused her death.*
- *Proof of paralysis, spinal tuberculosis, bone tuberculosis, monoplegia had to be demanded from Cipla.*
- *Proof of unknown steroid on an unknown dated had to be questioned.*

Point 16. It was observed that Smt.Kamini Barkur w/o Sh. Umeshchandra Barkur was hospitalised in M/s Maruti Nursing Home, Mulund, Mumbai for treatment of Cervical spondylitis & Stiff Neck and it is not a case of clinical trial as defined under Rule 122-DAA of Drugs And Cosmetics.

Note – Response by Complainant :

- *If it was a clinical trial under Rule 122-DAA of D & C Act, where is the question of criminal complaints before the Police and FDA.*
- *The point is that this drug could not be given for treatment of stiff neck. Stiff neck is not in indications of use.*
- *Dr.Mihirgiri Goswami has submitted to M.M.C. that the drug did not suit the complainant's wife. It was in MMC complaint file.*
- *Also had noted in in-patient record that joint pains occurred after Zoledronic acid.*
- *In direct contrast, has said in email that he administered the injection for joint pains.*
- *Transcripts of meeting on 22nd August 2014 with doctors were available in complaint file.*
- *Treating doctor said that it was one-day admission - Give today discharge tomorrow. That he will never give again.*
- *Dr.Dubey, ayurvedic doctor working as Medi-claim doctor for insurance company, also as A/Cs Officer for Maruti Nursing Home & also selling*

drugs illegally purchased to other hospitals and doctors, said that he goes to twenty-five hospitals.

- *For bone support this is a yearly injection. But he never realised that such serious reactions could happen. His target was to see that neither patient nor doctor had a problem. That he had to balance both.*
- *Who was Dr.Dubey to take responsibility of a drug manufactured by international company Cipla.*
- *Who gave him this responsibility other than Cipla.*

Point 17. In view of inadequate information available with respect to patient history, other drugs administered & sequence of events occurred after discharge of patient from Maruti Nursing Home, Mulund, clinical investigation reports as well as the exact cause of death (Post Mortem findings, if done); it is difficult to comment on whether there was lapse in the standard of care administered. Opinion of the concerned speciality expert's i.e. Rheumatologist, Intensivists, TB – Chest specialist etc. may be sought to ascertain this.

***Note – Response by Complainant** :*

- *Patient's history was noted by physician who certified her as "fit for Surgery". He had noted "Pre-morbidly healthy" "No addictions" "No known allergies" "No major illness in the past".*
- *List of drugs administered were in in-patient records.*
- *Sequence of events after discharge were in in-patient records of Platinum hospitals and Jupiter Hospital which were in Complaint file.*
- *Clinical investigation reports and exact cause of death were in Platinum Hospital & Jupiter Hospital in-patient records.*
- *Exact cause of death was in Bone Marrow Biopsy Report : "Aplastic Bone Marrow.*
- *There was no need of post-mortem report after 16 days in 3 hospitals.*
- *Investigators and experts were so confused with around **1500 pages** of in-patient records, affidavits of all parties, evidence documents, etc.*
- *There were two complaint files of State Commission as well as Maharashtra Medical Council.*
- *Rheumatologist's opinion was not required. Dr.Mihirgiri Goswami had noted in in-patient records "Post Zobone Arthralgia" meaning joint pains*

after injection Zoledronic acid. This was within 20 hours of injection Rokfos being administered and was a side effect of Rokfos.

Point 18. In this contest, Drugs Controller General, India has already written a letter vide ref No.PG/90/ADR/Rokfos/2018/DCG(I) dated 26/07/2018 to National Co-ordination Centre, Pharmacovigilance Programme of India, IPC, Ghaziabad and requested to examine the issue under PvPI and give their opinion to take necessary action in the matter.

Point 19. ADC(I), Public Grievance Cell, CDSCO, HQ, New Delhi has also written a reminder letter vide ref No.PG/90/ADR/Rokfos/2018/DCG(I) dated 10/09/2018 to National Coordination Centre, Pharmacovigilance Programme of India, IPC, Ghaziabad and requested to examine the issue under PvPI and give their opinion to take necessary action in the matter.

Note – Response by Complainant :

- *Opinion of IPC was sought by the following Officers under CDSCO :*
- *By DCG(I) on 26.07.2018.*
- *By ADC(I) on 10.09.2018.*
- *By DDC(I) on 30.11.2018.*
- *Again By ADC(!) on 05.12.2018.*

  (All evidence available)
- *They were telling the Secretary-cum-scientific Director Dr.G.N.Singh that the complainant is repeatedly writing and asking for compensation.*
  - *Note : I never asked for compensation.*
- *The very fact that they were using word compensation proves that criminal offence was committed.*
- *Vide letter dated 10th January 2019, Dr.G.N.Singh, Secretary-cum-scientific Director of IPC informed the Complainant, categorically stating "It may be noted that the Indian Pharmacopoeia Commission (IPC) is not the Regulatory authority to oversee and regulate matters related to Manufacturing, Sales and Clinical Trials induced adverse drug reactions/death. As such the grievance is not pertaining to IPC. Matters related to clinical trials and adverse drug reactions /death in this country are regulated by the Central Drugs Standards Control Organisation*

(CDSCO) under DGHS, Ministry of Health & Family Welfare, Govt. of India headed by Drugs Controller General (India).

I hope that with above information, the matter stands clarified from our end. ***(Dr.G.N.Singh).***

- *FDA Goa Director had refused to take action (Letter dated 15.05.2018) after false explanation by Cipla Head Global Pharmacovigilance and put the onus on DCG(I).*

  For a year FDA Goa Director did not take any action.

Note : Bogus Joint Investigation was a conspiracy hatched by DCG(I) and was conducted three weeks after Dr.G.N.Singh, Secretary-cum-Scientific Director, Indian Pharmacopoeia Commission refused to entertain CDSCO Drug Controllers' repeated requests from July-December 2018.

FDA Goa Director succumbed to corruption and absolved criminal offender, Cipla Limited the very next day after Joint Investigation Report.

Remarks by the Joint Investigation Team :

a) As per in Patient Records available with M/s Maruti Nursing Home, Mulund, Mumbai, it was observed that only single dose of drug Zoledronic Acid IV was administered to Smt Kamini Barkur on 09/06/2014 and said drug was not administered to her during her hospitalisation at Maruti Nursing Home till 14/06/2014.

Note – Response by Complainant :

There were no allegations of double dose. No need for repeating this over and over. This injection has to be given only once in a year even for bone cancer patients. It was given without patient's or relatives' consent.

b) It was observed that Smt. Kamini Barkur w/o Sh Umeshchandra Barkur was hospitalised in M/s Maruti Nursing Home, Mulund, Mumbai for treatment of Cervical spondylitis and stiff neck and it is not a case of clinical trial as defined under Rule 122-DAA of Drugs and Cosmetics Rules 1945.

Note – Response by Complainant :

- *That is exactly the point. This drug cannot be given for curing stiff neck in a single day. Stiff neck is not in indications of use sent by DGHS.*
- *If it was clinical trial under Rule 122-DAA, there is no question of police complaint.*

c) As complaint is related to adverse drug reaction, opinion of National Co-ordination Centre for Pharmacovigilance Programme of India IPC, Ghaziabad may be obtained to take necessary action in this matter.

d) Also opinion of the concerned speciality expert's i.e. Rheumatologists, intensivists, chest specialists etc. may be sought to ascertain lapses in the standard of care administered if any?

Note – Response by Complainant :

- *Investigators are confused. They have thrown the onus on IPC and experts on Rheumatism. They want post mortem report after 16 days in 3 hospitals.*
- *Bone Marrow Biopsy report was available.*
- *After this report dated 20th March 2019, CDSCO Subject Expert Committee (Analgesic & Rheumatology) - SEC held meeting on 11.04.2019.*
- *They opined that arthralgia, myalgia, bone pain and back pain are known side effects of Zoledronic acid.*
- *CDSCO Subject Expert Committee conveniently did not deliberate on other known side effects, petechial rashes and pancytopenia which are typical symptoms and characteristic features of Aplastic Anaemia. Patient died of Aplastic Anaemia.*
- *Such a massive cover up by CDSCO to protect criminal offenders, Cipla Limited and Maruti Nursing Home.*

WHAT WAS ENFORCED

Next day, on 21.03.2019, letter of pardon was given to Cipla Limited by third party, FDA Goa.

a) Changes in dates of Joint Investigation Report as well as Letter of Pardon is clearly visible.

b) This proves that it was a pre-planned conspiracy by CDSCO (HQ), CDSCO (WZ), Mumbai, FDA Maharashtra and FDA Goa Director.

Note : Nothing else was enforced.

SUBSEQUENT CORRESPONDENCE WITH FDA AND CDSCO

a) FDA Maharashtra Reply to RTI dated 16.10.2019; did not reveal Joint investigation conducted nine months earlier.

b) CDSCO Reply on Rheumatism dated 18.10.2019 also did not reveal Joint investigation.

Stated that regulatory issues in this case may be addressed by the licensing authority i.e. FDA Goa.

c) They were only passing the buck to and fro and trying to silence the aggrieved senior citizen to abort seeking justice in homicide of his wife.

PROOF OF SUB-STANDARD DRUGS MANUFACTURED AT GOA

US FDA warning to Cipla for Goa Plant. 12 serious violations of cGMP (current good manufacturing practices). Because your methods, facilities or controls for manufacturing, processing, packing or holding do not conform to cGMP, your drug products are adulterated.

- This media report is available with the Office of Lokayukta.
- Drug Rokfos which caused death of my wife was manufactured at Cipla Goa facility.

PATHETIC STATE OF FOOD AND DRUGS ADMINISTRATION IN MAHARASHTRA

MOS Health; Statement in Parliament – Maharashtra tops sub-standard drugs. **(Submitted to Lokayukta Office).**

- Drugs mixed with potato starch, corn starch and chalk.
- Drugs not containing prescribed ingredients.
- Injection Rokfos did not contain 5mg/100mL of Zoledronic acid.
- This is the reason that in spite of repeated requests and appeals, Cipla Drugs Safety Department at Mumbai did not investigate the drug.
- FDA Maharashtra colluded with Cipla and did not follow statutory guidelines.

CIPLA HAD PLEADED TO COMPLY WITH DIRECTIONS OF AUTHORITIES

a) Cipla had told the complainant vide letter dated 26th June 2018 that they will comply with the directions of the authorities as and when received.

b) They had all the authorities; CDSCO at Centre, FDA Maharashtra and FDA Goa in their pockets which is...

c) Exposed by this **Bogus Joint Investigation Report.**

CIPLA'S OFFICIAL REPORTING TO FDA, PVPI AND DCGI

Reply to my RTI Query by IPC dated 17.10.2019 says Cipla has reported to FDA, PVPI and DCG(I).

Letter dated 24th Nov 2017 says they do not have record of ADR.

FALSE EXPLANATIONS BY CIPLA LIMITED

- Linked imaginary diseases on the patient after their drug caused her death : Monoplegia, Spinal tuberculosis, bone tuberculosis and one paralytic arm. This was submitted without any evidence.
- Linked imaginary treatment to imaginary diseases : Anti-tubercular therapy. On an unknown date, she was administered unknown steroid for bone tuberculosis.
- They gave their explanation from sheer imagination.
- Cipla authorised representative said that they had immediately followed statutory guidelines and reported to FDA, PVPI and DCGI.
    - I have produced letters to the contrary from all the three authorities.
- Cipla pleaded ignorance of Schedule 'M' of Drugs and Cosmetics Rules.
- Ignorance of laws of the land is not an excuse in a homicide case punishable with life imprisonment.
- There was only one action to prove standard quality by sending sample to Govt Lab. Plenty of stock were available including four with treating doctor which were not produced during the raid.
- Sales Invoices were not produced.
- Matter has been deliberately not followed up by FDA Maharashtra officers as corruption was involved.

FDA GOA DIRECTOR'S U-TURN

FDA Director had told Cipla; I intend to take action deemed fit without prejudice to legal action which may be initiated against you. However, you are given an opportunity to submit your explanation in the matter, and to show cause, if any so as to why, I, should not take intended action against you.

Note – Response by Complainant :

- *Explanation was filled with totally blatant lies.*
- *She asked DCGI to take action.*
- *After a year, succumbed to corruption. Told Cipla ...*

  That explanation submitted by you was not satisfactory as you had failed to intimate to this directorate regarding serious ADR as required under Para (2) of Para 28 Schedule M of Drugs and Cosmetics Rules.

However, considering the assurance given by you that such violation will not be repeated and that on investigating the matter by the inspecting officer of this directorate no adverse findings were reported in respect of quality of the product, no action is taken against you.

However, you are hereby warned on the matter that, if such lapses are reported on your part in future, then strict action as per the provision of law will be taken against you.

RESOLUTION OF MY GRIEVANCE – WAS THIS SETTLEMENT OFFER, I DID NOT COMPREHEND THEN.

- CPGRAMS (Public Grievance) sent email dated 25th March 2019 asking for feedback on resolution of my grievance.
- However, did not inform me about Joint Investigation Report just five days ago.
- My reply to DCG(I) was that it was he, who has to order immediate cancellation of Cipla licence for playing with lives of citizens of India, nexus with doctors/private hospitals in conducting clinical trials on unsuspecting patients, deceiving FDA authorities, taking consumers for a ride and fooling the world with fake public claims. Cipla Chairman has to be booked and investigated by a Supreme Court monitored probe. It is several years now and it shows the pathetic state of affairs in government authorities, formed for the protection of citizens, are protecting criminals. These are crimes against humanity. They are playing with lives of citizens and you are just watching.

CABINET SECRETARY (INDIA)

Cabinet Secretary (India), along with around six to seven deputy secretaries went through around 240 pages of my complaint 'Cipla Drug Trial' and considered that it needs action.

- Accordingly asked the Health Secretary to take action.
- There has been no action for 1 year and three months now.
- Health Secretary did not inform Cabinet Secretary regarding Joint Investigation Report as it was a Fraud.

LOKPAL OF INDIA

Same explanation on Joint Investigation Report was submitted in my Complaint to Lokpal of India.

- There was no way, 5 officers in Ministry of Health and Family Welfare could be let off for this fraud on the citizens.
- Shockingly, Gross Misconduct on the part of the full bench of Lokpal.
- I have informed the PM, President, Speaker and Chief Justice of India demanding resignations of the Full Bench.
- That they have protected corrupted officers who in turn have protected criminal offenders.

CHIEF JUSTICE OF INDIA

NCDRC (NATIONAL CONSUMER DISPUTES REDRESSAL COMMISSION)

- Chief Justice of India has said that Live Streaming of Court Proceedings is crucial for the citizens to understand and be informed.
- In the wake of misconduct by the Lokpal, there is need for some sort of mechanism to be put in place to protect the rights of citizens.
- Misconduct by President of NCDRC has been submitted to the PM, President and Chief Justice of India. Video footage has been requested by me to prove my allegations against Justice R.K.Agrawal.
- There was only one incomplete statement by the Appellant when Justice R.K.Agrawal intervened to say that Aplastic Anaemia cannot occur in three days.
- Myself, the decree holder was questioned rather than the Appellants.
- File from State Commission was called for.
- My complaints with PM, President and Chief Justice of India are on record.
- Mental agony of a senior citizen seeking justice in death of his wife sacrificed as a 'Guinea Pig' has been prolonged by none other than the President of the Supreme Temple of Consumer Protection, Justice R.K.Agrawal.
- He has disgraced himself and his conduct as a former judge of the Supreme Court is exposed before the Nation.

DRUGS AND COSMETICS ACT, 1940

a) **Penalty under section 27 of the Act** – Any drug deemed to be adulterated or spurious when used by any person in diagnosis, treatment, mitigation or

prevention of any diseases or disorder is likely to cause his death or is likely to cause such harm on his body as would amount to grievous hurt withing the meaning of section 320 of the IPC solely on account of such drug being adulterated or spurious or not of standard quality as the case may be shall be punishable for a term which shall not be less than ten years but which may extend to imprisonment for life and shall also be liable to fine which shall not be less than ten lakhs or three times the value of drugs confiscated.

b) **[US FDA warning to Cipla for Goa Facility** – Because your facilities, methods and controls for manufacturing, processing, packing and holding of drugs do not conform to CGMP, your drug products are adulterated**].**

c) **Section 320 of the IPC – "Grievous Hurt"**

Any hurt which endangers life or which causes the sufferer to be during the space of twenty days in severe bodily pain or unable to follow his ordinary pursuits.

- **[**In the case of my wife within twenty hours she was bed-ridden, after five days unable to swallow, had bleeding rashes and bone marrow empty**].**

This was much greater than Grievous hurt.

DRAFT PHARMA POLICY OF MODI 01 GOVT IN 2015

a) As per media report by Reuters, a marketing ban of one year was proposed and confiscation of stock to be handed over to Government hospitals.

b) The authorities are aware of the immense malpractices by pharmaceutical companies and hence had correctly proposed the stringent Pharma Policy. Unfortunately, the Draft Pharma Policy was never enforced and implemented.

c) The Hon'ble Prime Minister has repeatedly warned pharmaceutical companies that their malpractices are forcing him to bring in a strict law.

d) I have investigated multiple malpractices and put before him for necessary, corrective action by the government.

INDIA NEEDS TO BE ALIGNED WITH THE DEVELOPED WORLD TO REACH THE STATUS OF A DEVELOPED NATION

a) A similar malpractice by Ranbaxy Laboratories Limited has been attached in my complaint to the Chief Justice of India, copy of which was sent to the

Hon'ble Lokayukta of Maharashtra. Charges on Ranbaxy by US FDA were exactly the same as Warning Letter to Cipla Limited in February 2020.

b) Ranbaxy had to plead guilty and had to pay US Dollars 500 Million to settle the criminal charges. In the case of Ranbaxy, no death was reported. Only falsification of data to FDA authorities.

c) In the case of Cipla, it was the case of nexus with doctors for trials with sub-standard drugs leading to unnatural, untimely and merciless death of my wife from serious adverse drug reactions from injection Rokfos hushed by around two dozen doctors at three hospitals.

d) Cipla violated statutory guidelines, did not investigate the said drug in spite of repeated requests and appeals by the aggrieved citizen.

e) I had asked Cipla to investigate in the interest of medical science to save precious lives as Zoledronic acid is used by millions across the world.

f) Cipla deceived FDA Goa Director with 'fake chemistry', 'fake medical theses', pleaded ignorance of the law relating to serious adverse drug reactions; Schedule 'M' of Drugs and Cosmetics Rules.

g) Cipla corrupted public servants in FDA, CDSCO, Public Health Departments, Deans and Professors of Government medical colleges, medical profession itself by indulging in 'fake science'.

h) Cipla Chairman, Shri Yusuf Hamied hoodwinked the world with false claims.

i) Cipla took an aggrieved senior citizen for a ride for seven long years.

j) Cipla threatened the senior citizen with defamation suits.

k) Cipla silenced media journalists investigating Cipla Drug Trial and interfered with freedom of the press.

SOCIAL MEDIA AS A TOOL FOR INFORMATION TO CITIZENS AND JUSTICE

a) Journalists and Senior Editors of leading Newspapers were keen of investigating this homicide.

b) Their voices were silenced by Seniors. I have emails and WhatsApp Chats from six leading media journalists.

c) I had to write two books :

- Addressed to the Hon'ble PM that his Vision for a New India is being destroyed.

- Book on "Cipla Drug Trial" shared with one and all in the government, both at the Centre and in the State of Maharashtra.

d) I had no option but to share my plight with fellow citizens on Twitter and Facebook.

e) I have posted 100 posters on Twitter and Facebook as a Serial which explains the homicide and the massive cover up by the government.

f) I have posted an open letter to the hon'ble PM on the eve of our 75th Independence day, explaining to him that we are not truly independent. That we continue to face tyranny of public servants who are supposed to protect us.

g) I have explained to Members of Parliament (six posters).

h) I have appealed to the youth of India regarding the dangerous network between pharmaceutical companies, doctors, FDA and CDSCO.

HAD TO TAKE ON THE ROLE OF AN INVESTIGATIVE JOURNALIST

a) 'Pharma Companies and Bribes for Prescription' – NDTV Expose by Sonal Mehrotra Kapoor was watched by me on TV. **August 12 2014.**

b) A day after NDTV's Expose showed doctors in Delhi agreeing to prescribe drugs in exchange for kickbacks, Health Minister, Dr.Harsh Vardhan said in Parliament that "unethical practices" will be urgently tackled and that "adequate action" will follow.

c) Dr.Jai Vir Singh, member of Medical Council of India said "It is the fault of the company also". Giving a bribe and taking a bribe are both wrong.

d) I had contacted the journalist and she called me on my mobile. But I had just started my investigation into death of my wife.

e) I took the clue from the journalist and recorded meeting between relatives and doctors on my mobile on **August 22 2014.**

f) The doctors revealed the truth that Rokfos caused serious adverse reactions never seen before.

g) Subsequent events to silence an aggrieved senior citizen is before the world in 100 posters on Twitter and Facebook.

h) It was the same Health Minister, Dr.Harsh Vardhan to whom Joint Investigation Fraud was communicated. He has not taken any action which proves that he has supported CDSCO officers in Ministry of Health and Family Welfare.

MERCY PETITION

I have written to the Hon'ble Prime Minister, Shri Narendra Modiji on 31st August 2021. That

a) I hoped and trusted the words of PM Modiji and I have been sadly betrayed.

b) It seems that all of the bureaucrats in Ministries and Departments, taking the aggrieved senior citizen for a ride for seven years had the backing of none other than the PM himself.

c) Nonetheless, I will pardon the PM considering his compulsions and priorities/disregard towards all types of citizens; Rich and Poor, Multinational companies vs the common man, etc.

d) After all, "Sabka Saath, Sabka Vikas" was a farce to dupe the common man and I as a common man fell for it for seven long years.
"Compulsion of PM towards billionaires?" "Aggrieved be granted Mercy Petition-Death by Euthanasia".

e) This will be much more "Honourable" than deceiving and hoodwinking citizens, colluding with criminals, anti-nationals and traitors to the nation.

f) At least, We will be remembered as "Laid life for Corrupted Democracy & Inhuman Govt"

HON'BLE LOKAYUKTA OF MAHARASHTRA

a) Joint Investigation fraud has to be placed before the Governor and Legislative Assembly of Maharashtra.

b) It has to be advised to; Chief Justice of India, Prime Minister of India, Speaker of Lok Sabha, President of India, Lokpal of India and Members of Parliament.

c) Action has to be taken against corrupted officers in FDA Maharashtra for gross misconduct in line of public duty, gross dereliction of duty and colluding with criminal offenders.

d) Bribes for Prescription had rocked the Parliament in 2014.

e) Cipla/Doctor/FDA/CDSCO dangerous nexus is far bigger and needs to be discussed in Parliament for an overhaul of the Health, Pharma and FDA sectors. Stringent laws have to be put in place.

PRAYER BEFORE THE HON'BLE LOKAYUKTA OF MAHARASHTRA

1. This grievance prejudicially affects citizens of the entire country.
2. Right to life cut short by Cipla and doctors.
3. Justice denied for seven years to a senior citizen by governments both at the centre and in the states of Maharashtra and Goa.
4. Officers at the helm of FDA and CDSCO indulging in dangerous network playing with lives of innocent citizens.
5. Each and every authority was compromised.
6. Level and extent of misconduct, gross dereliction of duty, colluding with criminal offenders by public servants is disgusting and disgraceful.
7. Unbelievable conspiracy to give letter that no action is taken against Cipla.
8. Conspiracy failed. FDA & CDSCO officers are trapped and dragged Lokpal full bench also.
9. Whole of India is consuming sub-standard drugs, investigated and exposed.
10. Human rights are sacred.
11. Multiple crimes by Cipla Limited :
    a) Playing with innocent lives in nexus with doctors.
    b) Caring a damn for lives lost from their drugs.
    c) Violating the laws of the land and then pleading ignorance of laws four years later.
    d) Taking aggrieved for a ride.
    e) Chairman hoodwinking the world with false claims.
    f) Silencing journalists investigating their crimes.
    g) Deceiving FDA Director with fake chemistry and fake medical theses.
    h) Bribing and corrupting public servants.
    i) Destroying the social fabric of our society.
    j) Each and every authority was compromised – FDA, CDSCO, Public Health Departments, Deans and Professors of government medical colleges, health profession itself.
12. My rights as a citizen in the largest democracy of the world has been denied.
13. I have been humiliated by one and all in the government.
14. Justice has been denied for more than seven years.

15. Fundamental rights necessary for existence in a civilised society has been denied by government authorities.

Request the hon'ble Lokayukta of Maharashtra for actions as requested above on Bogus Joint Investigation and Bogus Report.

Yours Sincerely,

Umeshchandra Barkur
(Complainant)
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