Complaints with FDA Maharashtra,Mumbai :

1. My complaint to FDA Maharashtra Joint Commissioner was dated 28th April 2015. I had also given my complaint addressed to Cipla dated 16/08/2014.
2. 16th December 2015 to FDA Assistant Commissioner regarding status of my complaint against Maruti Nursing Home.
3. I followed up with the Assistant Commissioner (Zone 4) on 16th November 2016.
4. On 25th November 2016, I submitted selective transcripts along with audio CD of meeting with the doctors on 22nd August 2014.
5. Subsequently, I met the Joint Commissioner, Mr.O.Sadhwani along with Dr.Metekar of FDA who told me that purchase was illegal and sale was illegal. There cannot be no defence by the owner doctors of Maruti Nursing Home that the drug was of standard quality. However the Joint Commissioner refused to entertain my plea saying that the drug causing death of my wife had to be proved in the Consumer Court.
6. I addressed my concern with the Commissioner of FDA vide email dated 29th April 2017.
7. On 14th August 2017, I sent an RTI query requesting whether FDA will initiate action on the said drug causing serious adverse side effects. Reply to this query was that the information sought was in Question & Answer Form. Further said that I can get information from 15th Court Mazgaon, Mumbai in case No.SW-1500166/2016.
8. 17th November 2017 – to Assistant Commissioner (Zone 4).
9. 17th November 2017 – to Joint Commissioner (Zone 4).
10. 20th November 2017 – RTI query.
11. 27th November 2017 to Joint Commissioner that the government is contemplating penalty for faulty products.
12. 14th December 2017 – Email by Assistant Commissioner (Zone 4) to come and inspect complaint file – case in 15th Court, Mazgaon.
13. 20th December 2017 – RTI query – Purchase bill for Rokfos (I had submitted in my complaint). This bill was not produced during raid by Drug Inspector on 22/07/2015.

14.22nd January 2018 – to Joint Commissioner – Copy of reply to my RTI query by DGHS dated 20/12/2017.

15.1st February 2018 – to Dr.Pallavi Darade, Commissioner of FDA – I addressed her that I have been following since three years.

16.8th February 2018 – Details of licence issued for drug Rokfos.

17.21st March 2018 – Whether FDA has taken action against Cipla for violation of Schedule M of Drugs and Cosmetics Rules requested by ADC(I) in their letter dated 15/02/2018.

18.2nd April 2018 – to First Appellate Authority – A drug manufacturer of another state outside Maharashtra has immunity to sell sub-standard drugs which causes a death and FDA Maharashtra will not even question the drug manufacturer.

19.2nd April 2018 – RTI Query – As a resident since birth of Maharashtra, Mumbai which is where the offence was committed, will FDA Assistant Commissioner Zone 4 register my complaint against Maruti Nursing Home for illegal drugs causing serious adverse reactions ultimately leading to my wife's death. YES OR NO?

20.2nd April 2018 – to FDA Commissioner – I asked for her confirmation that FDA Maharashtra cannot act against Cipla Limited as well as against Maruti Nursing Home in this cognizable and non-bailable offence.

21.25th April 2018 – I asked the Joint Commissioner regarding letters from the following authorities for action on my grievance addressed before them :

a) Letter dated 15/02/2018 from ADC(I) from office of DCG(I).
b) Letter No.1362/2018 from the office of Food, Civil Supplies and FDA Minister in respect of my grievance redressal to the Chief Minister of Maharashtra.
c) Letter dated 07/04/2018 from Medical Education and Drugs Section to FDA Commissioner for taking action in my complaint with the Prime Minister's Office.

22.10th May 2018 – to First Appellate Authority that reply was not received to RTI request dated 2nd April 2018. I received reply on 15th May 2018, while the reply was dated 03/05/2018 a) Information asked for was in Question & Answer form. b) In the complaint, it was not mentioned for illegal drug causing serious ADR ultimately leading to death of applicant's wife. c) This complaint was for

drugs sold above MRP. d) Drug Inspector has launched proceeding at 15th Court, Mazgaon. e) The firm Cipla is situated at Verna Ind. Estate, Goa. Hence licensing authority FDA Goa has jurisdiction to take action for violation of Schedule M of Drugs and Cosmetics Rules. f) There is no proof that the drug was sub-standard.

My response is as follows :

a) Information requested was regarding a homicide case and not for general knowledge.
b) Complaint states that my wife was taken in a critical condition after six days ultimately leading to her death. The Assitant Commissioner was given complaint addressed to Cipla to investigate drug Rokfos.
c) The Assistant Commissioner with whom my complaint was registered was arrested by the ACB.
d) What action at 15th Court, Mazgaon was taken for drugs sold above MRP?
e) Which part of my complaint is with Mazgaon Court?
f) Cipla's registered office is in Mumbai since 1935. As per Cipla, all product complaints are handled at Cipla, Mumbai and not at Cipla, Goa. This has been informed by FDA Goa Director to the DCG(I).
g) I had asked the Assistant Commissioner whether he will register my complaint against Maruti Nursing Home for illegal drugs causing serious adverse reactions ultimately leading to my wife's death? YES or NO? There is no reply to this query.
h) The Assistant Commissioner says that there is no proof of the drug being sub-standard. This assistant commissioner has all along in my visits to FDA office has been re-iterating to me that there was no proof of Rokfos being sub-standard. He is most concerned about Cipla.
i) Whose responsibility is it to prove that the drug was of standard quality? What is his role in FDA? Why did he send a sample in the year 2018 after Cipla was caught for violating Schedule M guidelines deliberately. The sample from the batch manufactured in Feb 2014 had to be sent for testing and not two years after the shelf life of the drug was over.

23. 18th May 2018 – First Appellate Authority - My detailed response as above was sent. Besides the initial complaint of 28th April 2015, I gave reference to the

multiple complaints as detailed above. Appeal heard but no meaningful explanation given by the Joint Commissioner and Appellate Authority.

24. 10th May 2019 – I sent certified copy of the Order by Maharashtra State Consumer Disputes Redressal Commission.

25. 12th June 2019 – That I am constrained to take necessary and appropriate action as advised to me.

26. 24th June 2019 – I addressed the matter to Maharashtra Minister for Food, Civil Supplies and Consumer Protection. That I am constrained to take necessary action as advised to me.

27. 13th September 2019 – I sent an RTI request for action against Cipla and Maruti Nursing Home for drug Rokfos causing death of my wife under section 27 of Druds and Cosmetics Act, 1940.

28. 19th October 2019 – I sent my appeal against reply to my RTI query dated 13th September 2019. Reply was clear abandonment of duty and responsibility. Action should have been under section 27 of the Act.

29. 28th October 2018 – Proof of corruption in FDA Maharashtra. I wrote to the DCG(I) giving proof of corruption in FDA Maharashtra, Mumbai at the highest level and proof of nexus between Cipla Limited and FDA authorities in death of my wife.

30. Proof of corruption in FDA has also been produced under my complaint addressed to the Hon'ble President, Hon'ble PM and Hon'ble CJI.

31. 16th December 2019 – I sent an RTI request to PIO of FDA Maharashtra asking him for 'Action Taken Report' on my complaint PMOPG/E/2018/0109827 (10/03/2018) as well as on letter of DCG(I) dated 15/02/2018 requesting action by FDA Commissioner against Cipla and doctors involved in death of my wife.

The PIO preferred not to reply to this RTI request. However, upon my complaint to the Hon'ble Chief Minister of Maharashtra reproduced under complaints to Chief Minister's Office/FDA Minister in my book, the PIO sent his reply to the above RTI request which was back-dated 27/01/2020 and which reached me on 06/02/2020, a clear deliberate delay of 18 days and violation under the RTI Act necessitating a penalty of Rs.250/- per day. This reply was hastily posted after my complaint to CM and FDA Minister. Request was of PMOPG complaint dated 10/03/2018 regarding ADRs of drug Rokfos and

action against FDA officials; Joint Commissioner, Assistant Commissioner and Drug Inspector for not taking action against the killers. Reply given was for complaint dated 06/07/2015.