Date : 9th July 2019

Dr.Henk Bekedam,

WHO Representative to India.

Dear Sir,

Subject: Serious adverse drug reactions of injection Rokfos manufactured by Cipla Limited causing death of my wife - Judgement delivered (Pages 21-40 of attachment) by Maharashtra State Consumer Disputes Redressal Commission.

This was a civil case against doctors and hospitals for 'Medical Negligence' and 'Deficiency in Service'. Criminal complaints before the Police, FDA authorities and CDSCO against Cipla / doctors / hospitals are pending since many years.

1. **This is my earnest appeal to you to inform WHO world-wide of the serious adverse drug reactions of Zoledronic acid, the ingredient of drug Rokfos.** This drug is manufactured by several pharma companies and used by cancer patients across the world. As per Cipla Chairman, Dr.Yusuf Hamied, there are 23 million cancer patients every year and India has a fair share of them.

2. Treating doctor has said that Zobone was his regular brand of Zoledronic acid and Rokfos was his new brand which caused the disaster. Also said that he is afraid to give now. That he will not give Rokfos to anyone again.

3. Serious Adverse Drug Reactions :

   a) Within 20 hours of administering this injection, the patient was in extreme bodily pains (arthralgia, myalgia, joint pain and bone pain).

   b) On the next day, she had difficulty in swallowing.

   c) She also had petechial rashes (bleeding from under the skin) on her arms and legs.

   d) On the next day she was in pancytopenia (WBC dropped from 20,000 to 2,300 and platelets from 143,000 to 95,000).

   e) Platelets fell from 95,000 to 59,000 on the next day.

   f) There was no action for five days at Maruti Nursing Home. The doctors watched the patient sinking to her death in order to protect the sub-

standard drug Rokfos from being exposed. Abruptly and in a panic they sent her to Platinum Hospitals. First blood counts after discharge from Maruti Nursing Home was WBC 200 and platelets 20,000. Bone marrow had failed at Maruti Nursing Home itself.

4. Pharmacovigilance (PV) is the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problem. The aims of PV are to enhance patient care and patient safety in relation to the use of medicines; and to support public health programmes by providing reliable, balanced information for the effective assessment of the risk-benefit profile of medicines.

5. The government of Shri Narendra Modi has launched a digital initiative under National Health Mission, Ministry of Health and Family Welfare (MoHFW) – Health Management Information system (HMIS) portal in five states of India. The visibility of health systems through reliable and real-time data is the need of the hour and with reliable data there is an increased transparency and accountability for informed decision-making said Ms Preeti Sudan, Secretary, Ministry of Health and Family Welfare.

6. Cipla Limited did exactly the opposite of what was required of them. The Ministry of Health and Family Welfare should take **action against Cipla Limited for Anti-pharmacovigilance**, multiple malpractices and criminal offences reproduced by me in the attachment.

7. The might and power of the pharma industry over FDA (Food and Drugs Administration) and Drug Control Authorities is on open display in this case.

8. I earnestly appeal to all the respected persons to whom I have addressed this letter to bring out the bare truth and harsh reality of this Network (Drug companies + doctors + hospitals + FDA authorities) before the Prime Minister for immediate action in the interest of the citizens of the country.

9. What is of grave significance is that, the known adverse drug reactions of Rokfos were suppressed for five days by doctors at Maruti Nursing Home including spine surgeon, Dr.Satyen Mehta. They watched the patient sinking to her death just to protect the sub-standard drug Rokfos from being exposed.

10. The doctors at Platinum Hospitals also suppressed the serious adverse drug reactions and colluded with Maruti Nursing Home.

11. At Jupiter Hospital where the patient finally succumbed to her death, the doctors too colluded with Maruti Nursing Home and Platinum Hospitals. A false death certificate was given deliberately as explained in the attachment.

12. This drug which has to be given only once in a year even for such serious diseases like hypercalcaemia of malignancy (cancer), bone metastasis (cancer), multiple myeloma (cancer), osteoporosis (after bone density tests, multiple precautions before and after administering this injection) was administered within seven hours of admission without any precautions and without the patient's or relatives' consent. As per treating doctor, he gave this injection for curing "Stiff Neck" (the reason for which my wife was admitted) in a single day.

13. Cipla Limited also suppressed the serious adverse drug reactions for four years in spite of repeated appeals to investigate in the interest of medical science.

- Protocol to be followed by pharma companies in cases of serious adverse drug reactions is as per letter from Directorate General of Health Services under Ministry of Health and Family Welfare **(Page 41).**

- Cipla did not investigate their drug Rokfos and did not follow mandatory provisions (Schedule M) of Drugs and Cosmetics Rules. The drugs were not recalled for obvious reasons – **FOUL PLAY** was involved.

14. The above nexus between the drug company Cipla Limited, doctors and hospitals was fully supported by Food and Drugs Administration authorities (FDA), the guardians appointed to ensure safe drugs with good quality and purity to the citizens of India.

15. FDA-Mumbai officials including the Commissioner have not acted against the doctors as well as Cipla Limited even though the drug sold illegally has caused a death. After the judgement by the State Commission implicating Cipla drug Rokfos for causing the death, FDA-Goa (which was where the drug was manufactured) are now trying to absolve Cipla of serious criminal offences of manufacturing sub-standard drugs (explained in detail in the attachment).

16. FDA-Maharashtra officials stating that they had no jurisdiction as the drug was manufactured at Goa itself shows that corruption was involved **(Page 42).**

17. Finally when law caught up with Cipla, the following false explanations were given to the Director of FDA-Goa and the complainant.

a) As per Cipla's letter to the complainant, treating doctor had informed them of the serious adverse drug reactions and they had immediately reported (Schedule 'M' provisions) to DCGI (Drugs Controller General of India), PVPI (Pharmacovigilance Programme of India) and FDA-Goa **(Page 43).**

b) These are totally false statements. Refer letters from all the three drug control authorities that Cipla had not informed them of the serious adverse drug reactions of injection Rokfos. No drugs were recalled **(Pages 44-47).**

c) On the other hand in direct contrast, Cipla in their explanation to FDA-Goa Director have feigned ignorance of Schedule 'M' reporting. Coming from an international drug company, this is shocking **(Refer page 48).**

d) Cipla lied blatantly to FDA-Goa Director on the health condition of my wife just to deceive her that Rokfos was not the cause of death.

The physician who had certified my wife **"fit for surgery"** (for cervical cord compression) had stated as follows in in-patient records **(Refer page 49)** :

- That patient was pre-morbidly healthy, no major illness in the past, no known allergies, no addictions.

On the contrary, Cipla projected my wife as having :

- Tuberculosis of spine (bone tuberculosis), Arm paralysis (Monoplegia), arthralgia **(Pages 51-52).** In fact as per medical records, arthralgia occurred after this injection was administered.

- On an unknown date, she had received one shot of steroids for tuberculosis treatment **(Page 52).**

- That this unknown steroid (anti-tubercular therapy) which was administered on an unknown date could also be the cause of aplastic anaemia or bone marrow failure (cause of death) **(Page 54).**

Note : There was no anti-tubercular therapy given. Cipla Limited created an imaginary "Thesis" – Aplastic Anaemia vs Anti-tubercular therapy. This false chemical / medical theory is Anti-pharmacovigilance to fool the scientists, doctors, medical profession and students of medicine and chemistry – **a serious anti-national activity.**

18. Judgement by the Maharashtra State Commission has to be brought before the people. FDA-Maharashtra officials have to answer why action has not been taken against the doctors of Maruti Nursing Home for the drug sold illegally causing a death. CDSCO has to be questioned why no action has been taken against Cipla Limited for suppressing the adverse drug reactions and violation of Drugs and Cosmetics Rules which mandated that the drug had to be recalled and tested for "standard quality". Also false statements to deceive FDA-Goa that Rokfos was not the cause of death. Rokfos causing the death has now been proved before the Maharashtra State Commission.

19. I have informed the Chief Secretary, Government of Maharashtra that I am constrained to take appropriate action as advised. Also to the Home Minister / Chief Minister and Minister for Food, Civil Supplies and FDA that no action has been taken on my police complaints and complaints to FDA-Maharashtra.

20. A common man cannot fight such injustice against such a formidable network. They are playing with innocent lives.

21. The bureaucrats in the department of pharmaceuticals had proposed a stringent pharmaceutical policy which is being reviewed by the law ministry since 2016. Central Drugs Standards Control Organisation (CDSCO) have also proposed amendments to Drugs and Cosmetics Act, 1940.

22. The Prime Minister, Shri Narendra Modi has voiced his concern for healthcare and has said in the past :

    a) Consumer protection, a must for the creation of 'New India'.

    b) Nexus between pharma companies and doctors for unethical monetary rewards should be broken.

23. The Health Minister, Dr.Harsh Vardhan has proclaimed that "Ayushman Bharat" is his first aim.

Hoping for co-operation from all the concerned persons and authorities addressed by me (for seeking justice) in raising this matter before the Hon'ble Prime Minister, Shri Narendra Modi. This will save and protect precious lives in the future.

Umeshchandra Barkur

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Cc : Dr.Harsh Vardhan, Union Minister for Health and Family Welfare.

Cc : Drugs Controller General of India.

Cc : Dr.G.N.Singh, Secretary-cum-Scientific Director, Indian Pharmacopoeia Commission.

Cc : Commissioner, FDA-Maharashtra.

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

Cc : Director, Health Services, Public Health Department, Mantralaya, Government of Maharashtra.

Cc : Ms Preeti Sudan, Secretary (H&FW), MoHFW.

Cc : Dr.Rajiv Kumar, Vice-Chairman, NITI Aayog.

Cc : Dr.V.K.Paul, Chairman, Board of Governors in Supersession of Medical council of India.

Cc : The Registrar, Maharashtra Medical Council.

Cc : Chief Secretary, Government of Maharashtra.

Cc : Management – Cipla Limited.

Cc : Maruti Nursing Home - Dr.Mihirgiri Goswami, Dr.Meghal Goswami, Dr.Aafaque Dolare, Dr.Satyen Mehta, Dr.Dubey.

Cc : Dr.Sanjith Paul – Platinum Hospitals.

Cc : Dr.Ajay Thakkar – Jupiter lifeline Hospitals Limited.