Cipla 171

Registered Post Ack. Due

Thursday, 31 May 2018

Shri. Umeshchandra Barkur
A-15, Neeta Apartments
Chaphekar Bandhu Marg
Mulund East
Mumbai-400 081

Your letter dated May 21, 2018 received on May 23, 2018 ("the Letter") addressed to the Assistant Drugs Controller (India) copy marked to Cipla Ltd. and letter dated May 28, 2018 received on May 29, 2018 ("the May 28 Letter") addressed to Cipla Management and copied to the Authorities

Dear Sir:

Further to our reply dated May 18, 2018, this reply sent on behalf of Cipla Ltd. ("**Company**") is in response to the Letter and the May 28 Letter, received from you.

The contentions, allegations and claims made in the Letter and the May 28 Letter are emphatically denied as they are incorrect, baseless and mala fide being contradictory to the facts available on record. Nothing in this reply shall be construed to be in admission of any averment made in the said letters, unless specifically so stated in this response. Without prejudice to the foregoing denial, we strongly refute the ex facie false and baseless allegations made in para 14 g) of the Letter against our Global CEO & MD and hereby place on record that he was not even in the service of the Company at the relevant point in time and in fact neither was the Head-Pharmacovigilance whom you repetitively referred to in your recent communications. This characterises the outrageous and baseless nature of the allegations made by you in your protracted communications which we repeat is causing us serious harassment.

In this regard we request your attention to your letter of April 18, 2017 in which you state *"I am not accusing Cipla in any manner."* We are perplexed and fail to understand your abrupt change of tactic to unlawfully allege and defame the Company before the Hon'ble food and drug authorities and governments, four years after the sad demise of your wife and absent any change in circumstances or developments whatsoever. Your attempt is clearly an afterthought to coerce the Company to give in to your illegal demands.

It is critical to note the total lack of clarity on whether it was indeed "Zobone" or the Company product IV Rokfos ("**IV Rokfos**") was administered to the patient as also admitted by you in your emails addressed to the Company.

Irrespective of and without prejudice to the status shown in the immediately preceding para., it is true that prompted by your complaint, the Directorate of Food & Drugs Administration, Goa ("**FDA, Goa**") initiated inquiry with the Company in which our Company had appropriately assisted the FDA, Goa, in all its interrogatories and concerns regarding the Company's manufacturing plant and IV Rokfos. The Company asserts that the issue has been dealt with by the FDA, Goa, demonstrating that your allegations are without basis apart from being false.

Cipla Ltd. R & D Centre, LBS Marg, Vikhroli West, Mumbai - 400 083.
Phone (022) 2576 1800, 2575 6000

Cipla Ltd. Regd. Office Cipla House, Peninsula Business Park, Ganpatrao Kadam Marg, Lower Parel, Mumbai - 400 013
Phone +91 22 24826000 Fax +91 22 24826120 E-mail contactus@cipla.com Website www.cipla.com
Corporate Identity Number L24239MH1935PLC002380

It is pertinent to here record that for the past four years, your grievance has been solely against Maruti Nursing Home, Mulund, and its administering doctors. You have elected not to include that establishment in addressing the referenced letters and instead maliciously and falsely attempting to implicate the Company in the controversy, in a frivolous and vexatious attempt.

For clarity and reference, we are providing a para-wise reply to the contents of the Letter.

Para 1: We categorically deny your false contention of a nexus with Maruti Nursing Home on sale of IV Rokfos or otherwise.

Para 2: As the Company manufacturing unit of IV Rokfos is situated in Goa, apparently FDA, Maharashtra had forwarded your complaint to FDA, Goa. As earlier stated, FDA, Goa has conducted its investigation and the issue have accordingly been dealt with. Accordingly, your demand that FDA, Maharashtra now take any action in the regard is mala fide and vexatious apart from it being an afterthought.

Para 3: The Company denies any "nexus into sale of sub-standard drugs" as alleged either with regard IV Rokfos or otherwise. Your allegation is false and baseless. As regards the rest of the contents, the Company reiterates that it is neither aware of nor concerned with the issues raised by you against Maruti Nursing Home or the doctors.

Para 4: It is of record that you admitted that since the Company manufacturing is situated at Goa, you had raised your grievances to the Department of Public Grievances, Goa, You have now in the preceding paragraphs of the Letter requested the FDA, Maharashtra to take action. Clearly, you have addressed your previous complaints to FDA, Goa which have been dealt with.

Para 5: It is once again reiterated that on completing its investigation, the FDA, Goa has concluded that no infirmities were found in the manufacturing process of IV Rokfos or that any complaints were received for the said product. This is absolutely without prejudice whether it was indeed "Zobone" or the Company product IV Rokfos ("**IV Rokfos**") was administered to the patient.

Para 6: The allegations and contentions in the letter dated May 9, 2018 addressed to the Company's senior management are false and frivolous and despite the Company offering its assistance to you at all times and having conversed with you over telephone. This letter was adequately replied to on May, 18 2018, copy attached for reference. For the first time after four years you have sought to impute blame on the Company for the unfortunate demise of your wife, as a afterthought. Take notice that none of the Company's senior management, to whom you have addressed that letter are neither involved with the issues raised by you in any manner whatsoever nor with the day-to-day management of the Company in this regard. It is apparent that your motive is to malign, and pressurize the Company into giving into your illegal demands.

Para 7: The Company denies any foul play or malpractice at its manufacturing plant or any nexus with Maruti Nursing Home or its doctors. As mentioned, FDA, Goa visited the Company Goa manufacturing plant and issued an inspection report clarifying in no uncertain terms that no infirmities have been found in the manufacturing process. Your allegations are therefore absolutely unfounded. It is strongly denied that IV Rokfos is a sub-standard drug or that our Company has been involved in its use as a clinical trial to cure stiff neck in a day or at all, as unequivocally stated in the prescribing information (PI) material shared with you by the Company. Administration of IV Rokfos was never authorised/promoted for curing stiff neck nor was IV Rokfos involved in any clinical trial as alleged by you.

Cipla Ltd. R & D Centre, LBS Marg, Vikhroli West, Mumbai - 400 083.
Phone (022) 2576 1800, 2575 6000

Cipla Ltd. Regd. Office Cipla House, Peninsula Business Park, Ganpatrao Kadam Marg, Lower Parel, Mumbai - 400 013
Phone +91 22 24826000 Fax +91 22 24826120 E-mail contactus@cipla.com Website www.cipla.com
Corporate Identity Number L24239MH1935PLC002380

Para 8: The malpractices alleged are absolutely denied as fully false and baseless, made with an intention to intimidate the Company.

Para 9: You will agree the Company is a well-known pharmaceutical major, manufacturing and supplying quality products at affordable prices to its consumers in India and throughout the world. The Company has at every instance offered you assistance whenever you have addressed any letter or email to it and in telephone call to you. Immediately on receipt of your first communication from the treating physician, the Company duly complied with all statutory procedures. A safety investigation was carried out and was dully reported to the DCGI in all on six different instances. It would not be out of place to mention here that the treating doctor did not raise any concerns as to the quality of the product and corroborated that the incident was not drug related and accordingly the Company had not suspected any product quality issue.

Para 10 & 11: The assumptions made by you in these paragraphs are baseless and frivolous and a mere desperate attempt to somehow impute liability to the Company and that to as an afterthought after 4 years. The Company denies that it did not carry out any investigation. In fact, immediately after receiving information from Dr. Mihirgiri Goswami, Company representatives followed a procedure in speaking on telephone with the treating doctor, Dr. Mihirgiri Goswami who informed that the late Smt. Kamini Barkur was suffering from spinal tuberculosis and that her one arm was paralytic; annotated in the telephone record form ("**TRF**") on August 7, 2014. Later following pharmacovigilance guidelines six CIOMS forms were submitted on August 20, 2014, Sept. 08, 2014, July 21, 2016, May 2, 2017, March 7, 2018 and May 22, 2018 to the DCGI. Therefore, your allegation on attempts to suppress material whether of the alleged adverse drug reactions or otherwise is clearly devoid of any merit and denied.

Para 12: The nature of the death would be recorded in the death certificate.

Para 13: The contents of this para. does not concern the Company, save and except that ambiguity on whether "Zobone" or IV Rokfos was administered to the patient is reiterated; purchase from a licensed stockist cannot confirm that ADRs had occurred; the claim that Maruti Nursing Home doctors were induced by the Company to prescribe and sell IV Rokfos instead of Zobone is vehemently denied as being false.

Para 14:

a. None of your emails prior to May 2018 reported that the incident was drug related and merely claim ADRs which is a mere conjecture particularly given the lack of certainty of use of IV Rokfos, as also admitted by you in your emails;

b. the treating doctor at Maruti Nursing Home did mention ADRs but declined to fill-in the ADR form as according to him incident was not drug related, as recorded in the TRF. Your emails did not report the incident to be drug related.

c. The indications of Zoledronic Acid were sent to you to give you information of the Company product Rokfos which in no manner qualifies for a confirmation of the ADR's as wrongly alleged by you.

d. The question of contesting the ADR's was nowhere in question since the treating doctor had informed us that the incident was not drug related and the same was already recorded in the TRF. Your email to us merely requested for assistance which was provided to you when asked including send the Product Information as was requested by you..

Cipla Ltd. R & D Centre, LBS Marg, Vikhroli West, Mumbai - 400 083.
Phone (022) 2576 1800, 2575 6000

Cipla Ltd. Regd. Office Cipla House, Peninsula Business Park, Ganpatrao Kadam Marg, Lower Parel, Mumbai - 400 013
Phone +91 22 24826000 Fax +91 22 24826120 E-mail contactus@cipla.com Website www.cipla.com
Corporate Identity Number L24239MH1935PLC002380

e. As regards your contentions of the alleged faulty manufacturing practices allegedly reported by the US FDA, apart from being false and baseless, we state that the same are absolutely irrelevant and have no bearing whatsoever to the issue at hand.

f. As stated earlier, the Company had immediately informed the appropriate licensing authority of the adverse event. Similarly, the explanations given to the FDA, Goa on non-compliance of Schedule 'M' has no relevance to the issue at hand. In any event, our explanation has been accepted by the FDA, Goa and has been adequately dealt with.

g. As mentioned above, we refute the false and baseless allegations made in para 14 of your Letter as the same has been dealt with above. As regards, to the rest of the allegations i.e. we 'lied' and deceived' the FDA, Goa, the same are baseless, false and denied and per se defamatory and in utter disregard of the truth. We state that the Company's medical services team had a telephone call with the administering doctor on August 7, 2014 at 14:58 hours, it was informed to us that your wife suffered from spinal tuberculosis and that her one arm was paralytic and one shot of steroid was given for tuberculosis treatment. This is also recorded in the TRF dated August 7, 2014 maintained by us. We had merely informed the FDA, Goa and DCGI, the information that we had received from the administering doctors.

h. We state that IV Rokfos is in fact used for osteoporosis. The fact that your wife was not admitted for osteoporosis has nothing to do with us or our product. If the administering doctor were to administer IV Rokfos to a patient not suffering from osteoporosis, we cannot be held liable for the same. We therefore deny any foul play as falsely alleged by you. It is also stated that it is the treating doctor's legal and ethical responsibility to ensure that he uses any drug as per its therapeutic indications. Cipla has clearly and unambiguously mentioned in IV Rokfos prescribing information about the nature of the product, its sphere of action, pre-requisite laboratory tests, the possible side-effects, adverse drug reactions, interaction with other drugs, etc., a copy of which was also sent to you.

Para 15, 16 & 17:

We submit that the contents do not concern us. In any event, you have merely repeated the same false and baseless allegations again. For the sake of brevity, we reiterate all that has been stated by us hereinabove in this regard.

Para 18 & 19:

We state that there is no material whatsoever to substantiate your false and baseless allegation that IV Rokfos is a sub-standard drug and we demand that this false and baseless allegation be withdrawn. IV Rokfos is being used by thousands of people. Further, we deny that any representative of the Company, whether Dr. Kakade or anybody else has given any false information about your wife. The question therefore of any action being taken in this regard does not and cannot arise. In view of what has been stated hereinabove, your claims in paragraph 19 is also false, baseless, meritless and frivolous. To seek cancellation of our license/ confiscation of our products on such frivolous grounds raised by you in your Letter are groundless threats and appears to be a clear attempt to extort..

With reference to the rest of the paragraphs, the contents thereof do not warrant any response from the Company.

Further with reference to the May 28 Letter, while we strongly refute all the allegations made therein, it is absolutely baseless to state, that the Company has threatened you in any manner. In view of your false and frivolous allegations before the state and central authorities, the Company is compelled to protect its interest by taking appropriate legal recourse. Further your allegation that there has been nexus between the doctors of Maruti Nursing Home and the Company is false to your knowledge and is vehemently denied. The Company has never defended any faulty or wrongful treatment. It is also denied that the Company has ever induced the doctors of Maruti Nursing Home to sells it brand or to promote IV Rokfos to other hospitals and nursing homes or has manufactured any batched of the product, IV Rokfos specifically to be supplied to Maruti Nursing Home, as alleged or at all. You have once again in your May 28 Letter reiterated that the treating doctor has noted Post Zobone Arthalgia. You are aware Zobone is not a Company drug product. Applicable provision of Schedule M of the Drugs and Cosmetics Rules (referred by ypu) relates to reporting to the licensing authority, which the Company has complied with in having informed the DCGI (the appropriate licensing authority) the Pharmacovigilance Program of India and later FDA, Goa. IV Rokfos was never subject to clinical trial in 2014 or earlier or thereafter as falsely and baselessly alleged by you. We state that the contents of the May 28 Letter are merely repetitive and therefore warrant no further response and our responses to the repeated allegations and contentions shall abide in the ones already stated against them in our earlier response. The Company shall, premised on these valid grounds and facts, rigorously contest any false and egregious civil or criminal action foisted on the Company as threatened by you.

Trust the valid and substantial grounds in our replies refute the false and baseless allegations put forward by you against the Company and its product in entirety. Further, the Company has been empathetic enough with you ever since and that you have been provided with the complete information as requested.

We observe that the contents of the May 28 Letter is merely repetitive in nature to that of the Letter (and of your earlier communications) and a mere habitual and recurring attempt on your part to illegally and wrongfully impute liability to the Company. Given the prolixity of your communication of repetitive content and to save itself the resultant harassment, our Company reserves its right to not to respond to any further correspondence from you and comply with directions of the authorities as and when received.

We are constrained to mark copies of this reply to FDA, Maharashtra, Mumbai; Directorate of FDA, Goa; Directorate of Public Grievances, Govt. of Goa; Directorate of Health Services, Mantralaya, Govt. of Maharashtra; as you have claimed to have copied the referenced letters to them.

Yours truly,

For Cipla Limited

Authorised Representative

cc to:

1. Food and Drugs Administration, Maharashtra, Mumbai
   M.S. Survey No. 341, Bandra-Kurla Complex
   2nd floor, Bandra (East), Mumbai-400 051

Cipla Ltd. R & D Centre, LBS Marg, Vikhroli West, Mumbai - 400 083.
Phone (022) 2576 1800, 2575 6000

Cipla Ltd. Regd. Office Cipla House, Peninsula Business Park, Ganpatrao Kadam Marg, Lower Parel, Mumbai - 400 013
Phone +91 22 24826000 Fax +91 22 24823120 E-mail contactus@cipla.com Website www.cipla.com
Corporate Identity Number L24239MH1935PLC002380

Cipla 176

2. Director, Directorate of Food and Drugs Administration, Goa
Dhanwantari, Opposite Shrine of the Holy Cross,
Bambolim-Goa-403 202

3. Directorate of Public Grievances, Government of Goa.
4th Floor, Udyog Bhavan
Opposite Police Head Quarter
Azaad Maidan, Panaji, Goa

4. Directorate of Health Services, Mantralya, Government of Maharashtra
Arogya Bhavan, St. George's Hospital Compound,
P.D'Mello Road, Mumbai-400 001

Cipla Ltd. R & D Centre, LBS Marg, Vikhroli West, Mumbai - 400 083.
Phone (022) 2576 1800, 2575 6000

Cipla Ltd. Regd. Office Cipla House, Peninsula Business Park, Ganpatrao Kadam Marg, Lower Parel, Mumbai - 400 013
Phone +91 22 24826000 Fax +91 22 24826120 E-mail contactus@cipla.com Website www.cipla.com
Corporate Identity Number L24239MH1935PLC002380