780

Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
(Public Grievance Cell)
FDA Bhawan, Indrajit Gupta Road, New Delhi

भारत सरकार
स्वास्थ्य सेवा महानिदेशालय
केंद्रीय औषधि मानक नियंत्रण संगठन
औषधि नियंत्रक कार्यालय (भारत)
लोक शिकायत डिवीजन, एफ डी ए भवन,
इंद्रजीत गुप्ता रोड, नई दिल्ली -110002

F.No. PG/90/ADR/ROKFOS/2018/DCGI

Dated: 20/04/2021

To,
Mr. Umesh chandra Barkur,
A-15, Neeta Apartments,
Chaphhekar Bandhu Marg,
Mulund East, Mumbai- 400081.

Sub: -Public Grievance; related to adverse drug reaction (ADR) of Zoledronic acid IV infusion (5mg/100ml) [Brand : ROKFOS; manufactured by M/s Cipla Ltd., Verna Industrial Estate, Verna, Goa]; reg.

Sir,

This is with reference to your current representation(s) received from the Drugs Regulation section, MoHFW vide e-mail dated 08.02.2021, 11.03.2021, 16.03.2021, regarding the subject cited above.

As per various communications received at this office, your wife was admitted to M/s Maruti Nursing Home, Mulund, Mumbai due to suffering from Stiff Neck and Cervical spondylitis. Your wife started complaining of severe arthralgia, myalgia, bone pain following administration of "**Zoledronic acid (5mg/100 ml) IV infusion**" (Brand : Rokfos, manufactured by. M/s Cipla Ltd, Goa) at the said Nursing Home. Finally, she expired on 24.06.2014. You complaint that the sad demise of your wife was an untimely and unnatural death due to administration of "Zoledronic acid (5mg/100 ml) IV infusion" (Rokfos Mfgd. by. M/s Cipla Ltd, Goa) at the said Nursing Home. In This connection the latest communications as referred above were further examined at various level in this office. Having further examined, I am directed to convey the following narrative;

1. You had filed your case through e-mail dated 01.01.2018 to FDA Goa questioning the quality of drug "Zoledronic acid (5mg/100 ml) IV infusion" [Brand : ROKFOS].
2. In response to the said e-mail, the FDA Goa vide letter No. 31/DFDA/4A 2017-18/325 dated 16.4.2018, had informed you that the matter was investigated by their Inspecting Officers by visiting the premises and the status was communicated to you. Thereafter, the firm M/s Cipla was called for personal hearing on this subject and the copy of explanation from M/s Cipla ltd. Verna industrial Estate, Verna, Goa was forwarded to you as annexure to the said Letter.
3. The FDA Goa vide their Letter no. 31/DFDA/4A 2017-18/883 dated 15.5.2018 acknowledged CDSCO that the complaint was investigated by the investigating officers of FDA-Goa by visiting the premises and reported that all ADR related complaints are investigated at Drug Safety Deptt. of M/s Cipla, Mumbai according to their Company's Policy and subsequent follow up reports are submitted to DCGI as per Pharmacovigilance guidelines. It was also stated that the said adverse drug reaction(ADR) case was not reported to FDA Goa.
4. Later on, the firm was served with a show cause notice and was personally heard in the matter by the state Drugs Control authority (FDA –Goa). As it was a serious adverse drug reaction case, copy of complaint and submission from Cipla along with reply from complainant on explanation submitted by Cipla were forwarded to CDSCO for information and necessary action.
5. In response, CDSCO vide Letter no. F. No. PG/90/ADR/Rokfos/2018/DCGI dated 09.07.2018 had requested the FDA Goa to intimate about final decision taken by FDA Goa, for initiating further necessary action/decision in this matter.

6. Subsequently, the DCG(I), CDSCO (HQ) requested FDA –Goa [vide F. No. PG/90/ADR/Rokfos /2018/DCGI dated 19.03.2019] to take appropriate action under the provisions of Drugs and Cosmetics Act, 1940 and Rules 1945 considering that the response of the firm to the Show Cause Notice was not satisfactory, as FDA –Goa being the Licencing Authority for "drugs" .
7. Further, in response to your grievance application filed through CPGRAM portal, this office had communicated [Vide letter No. F. No.PG/90/ADR/Rokfos/2018/DCGI dated 20.03.2019] that your case was under examination and active consideration with CDSCO & State Drugs Control Authority (FDA Goa) for further action.
8. In the meantime, a Joint Investigation team comprising of the officers deputed by CDSCO (West Zone-Mumbai office) and FDA (Maharashtra) along with Experts from Pharmacology Department, (Lokmanya Tilak Municipal Medical College & General Hospital, Mumbai) conducted further investigation on 29.01.2019 & 01.02.2019 at M/s Maruti Nursing Home, Mulund, Mumbai.
9. As per the above Joint Investigation report, the officials from FDA-Maharashtra had already inspected on 24/05/2018 at the premises of M/s Novacare Drugs Specialties Pvt. Ltd., 14 & 15, Vardhaman Complex, L.B.S. Marg, Fitwell Compound, Vikhroli (W), Mumbai and reported that the stock of the implicated drug, Rokfos Injection IV (B No V4006) was not found in the said premises of M/s Novacare Drugs Specialties. However, stocks of other batches of Rokfos Injection IV was found and accordingly, Drugs inspector, (FDA-Maharashtra) collected and forwarded the sample of Batch No. GI70312 to the Government Analyst, Food and Drugs Control Laboratory, Mumbai, Maharashtra for the purpose of test and analysis including test for toxicity.
10. The Govt. Analyst, Drugs Control Laboratory, Maharashtra vide report No. STD/MUM/106142/2018 dated 12/09/2018 declared the sampled drug to be of "Standard Quality" and was also found meeting the "test for toxicity".
11. The below mentioned statement is being quoted from said Joint Investigation team report for your reference please.

    "In the 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 the said drug was not administered to her again during her hospitalization at M/s Maruti Nursing Home till 14/06/2014. It was observed that your wife Smt. Kamini Barkur was hospitalized in M/s Maruti Nursing Home, Mulund, Mumbai for treatment of Cervial- Spondilysis & Stiff Neck and it was not a case of clinical trial as defined under Rule 122-DAA of Drugs And Cosmetics Rules 1945".
12. The issues related to Zoledronic Acid (5 mg/100ml) for Infusion was also deliberated in Subject Expert Committee (SEC) Analgesic & Rheumatology on 11.04.2019 at CDSCO (HQ). The Committee deliberated the matter & opined "the reported adverse reaction like arthralgia, myalgia, bone pain etc. are known side effects of Zoledronic Acid. However, regulatory issues in this case may be addressed by the Licensing Authority" .
13. Finally, FDA Goa vide letter No. 31/dfda/4a/2017-18/117 dated 29.05.2019, informed CDSCO that the firm M/s Cipla had been warned that if such lapses are reported on the firm's part in future, then strict action as per the provisions of law will be taken against the firm.

Thus, the matter has been investigated, examined & inspected at various levels viz. FDA Maharashtra, FDA Goa & CDSCO and action has been taken accordingly as mentioned above.

This is being issued with the approval of the competent Authority

आपका आभारी/ Yours faithfully,

(सोमनाथ बसु)/ **Somnath Basu**

सहायक औषधि नियंत्रक (भारत)/ **Assistant Drugs Controller (I)**

Copy to:-

1. Under Secy., Drugs Regulation Section, MoHFW, Nirman Bhawan, New Delhi w.r.t. letter no. X.11035/308/2020-DRS dated 09.10.2020 and email dated 16.03.2021, 11.03.2021, 08.02.2021, for kind information.

20/04/2021