

Reg. A/D
Ph : (0832)-2459230/ 2459226
Fax : (0832)-2459223
Website: www.dfda.goa.gov.in
Email ID:- off-dfda.goa@nic.in

No. 31/DFDA/68B/ Vol -7/2017-18/ 6658
Government of Goa
Dte, of Food & Drugs Admn.,
"Dhanwantari"
Opp Shrine of the Holy Cross,
Bambolim, Goa 403 202.
Dated:- 4/02/2022.

To,
Drugs Controller General (India),
Directorate General of Health Services,
Central Drugs Standard Control Organisation,
(Public Grievance Cell),
FDA Bhawan, Kotla Road,
New Delhi-110 002.

Sub: Public grievance; of Mr. Umeshchandra Barkur related to adverse drug reaction of drug Rokfos IV infusion (Zoledronic acid (5mg/100ml) manufactured by M/s. Cipla Ltd., Verna Industrial Estate, Verna-Goa.

Ref. No. :-Your letter No.PG/90/ADR/ROKFOS/2018/DCGI dated 17/01/2022

Sir,

This has reference to your above referred letter on the subject mentioned above wherein, you have requested to examine the matter and take appropriate action under intimation to your office and to the complainant.

In this regards, it is informed you that this Directorate had received a complaint from Mr Umeshchandra Barkur on the said subject via email on 01/01/2018 regards Rokfos Injection, B. No. V40056, Mfg. date 02/2014, Exp. Date 01/2016 manufactured by M/s. Cipla Ltd., Verna Industrial Estate, Verna-Goa; almost two years after the expiry of the product. The Manufacturing firm was inspected on 11/01/2018 by the Inspecting Officer of this Directorate to investigate the complaint with respect to quality issue and to verify any non-compliance of Schedule M of Drugs Rules 1945.

[Signature]

Contd..2/-

No non-compliance was reported on the part of the manufacturer; except that the firm had failed to report ADR to this Directorate in violation of sub para 2 of para 28 of Schedule M of Drugs Rules, 1945. Firm was issued Show Cause Notice (Copy enclosed) and on receipt of the reply from the firm and submission made that in future all ADR cases will be intimated to this Directorate along with CDSCO and PVPI; no action was initiated against the firm and was warned in the matter. (Copy enclosed).

Further the matter was intimated to your office vide letter no. 31/DFDA/4A/2017-18/117 dated 04/04/2019 & 31/DFDA/4A/2017-18/1235 dated 29/05/2019 (Copies enclosed). Thus you will appreciate, that this Directorate has acted promptly on the complaint; and taken necessary action in the matter.

This is for your information.

Yours faithfully,



(Jyoti J. Sardesai)
Director, Food & Drugs Admn.

Enclosed :- As above.

Copy to:
Mr. Umeshchandra Barkur,
A-15, Neeta Apartments,
Chaphekar Bandhu Marg,
Mulund, East Mumbai 400081

✓
"Wear Mask
02/02/2022 Let DC Jay

Maintain Hand Hygiene

Follow Social Distancing"