

RPAJ

नोंदणीकृत डाकेने

महाराष्ट्र शासन

क्रमांक : संकीर्ण-२०२०/सं.क्र.९७१/औषधे-२
 वैद्यकीय शिक्षण व औषधी द्रव्ये विभाग,
 गोकुळदास तेजपाल कॉम्प्लेक्स इमारत,
 ९ वा मजला, लोकमान्य टिळक मार्ग,
 मंत्रालय, मुंबई-४०० ००१.
 ई-मेल : sandesh.sawant@nic.in
 दिनांक : ११.०२.२०२०.


प्रति,

श्री.उमेशचंद्र चंदू बरकूर,
 अ-१५, नीता अपार्टमेंट्स,
 चाफेकर बंधु मार्ग, मुलुंड (पुर्व),
 मुंबई - ४०० ०८१.

विषय : तक्रारदार श्री.उमेशचंद्र बारकूर यांनी मा.लोकआयुक्त यांचेकडे सन २०१४ मध्ये मारुती नर्सींग होम, मुलुंड, मुंबई येथे उपचार दरम्यान मे.सिपला ड्रग्स, प्रा.लिमिटेड कंपनीच्या रॉकफ्रॉस या औषधाने तक्रारदार यांच्या पत्नीचा मृत्यु झाल्या प्रकरणी ग्राहक न्यायालयाने माहे मे २०१९ मध्ये आदेश दिले असून औषधी द्रव्ये विभाग, महाराष्ट्र यांनी संबंधित दोषी डॉक्टर यांचेवर कार्यवाही करणेबाबत तक्रार.

संदर्भ : कक्ष अधिकारी (टे-९), लोकआयुक्त कार्यालय, मुंबई यांचे पत्र .लोआ/कॉम/४१५६/२०१९/
 (टे-९) ६९३/२०२१, दिनांक १८.०१.२०२१.

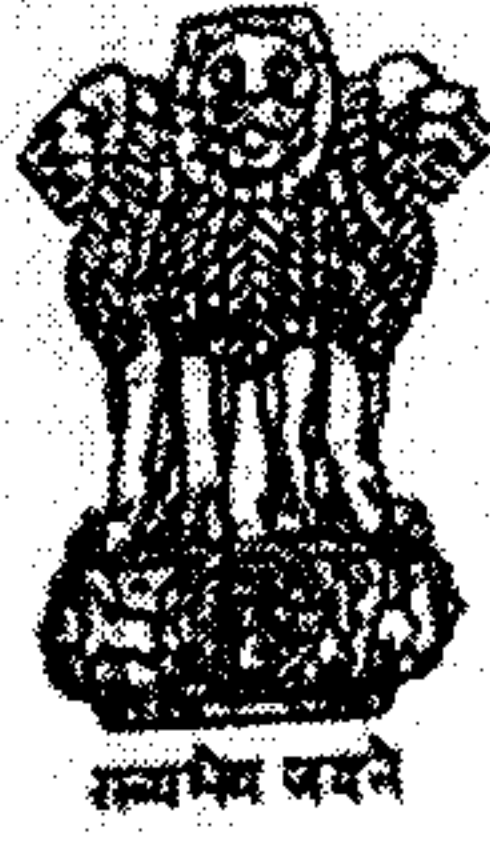
उपरोक्त विषयांकित प्रकरणी मा.लोक आयुक्त यांचेसमोर दिनांक ३०.१२.२०२० रोजी झालेल्या सुनावणीमध्ये प्राप्त झालेल्या निदेशानुसार 'सिपला' या औषधी कंपनीविरुद्ध कारवाई करण्यासंदर्भात भारत सरकारच्या स्तरावर गठीत समिती व त्यासंदर्भातील संबंधित कागदपत्रे या पत्रासोबत जोडून पाठविण्यात येत आहेत (प्रती संलग्न).


 (हेमंत महाजन)

अवर सचिव, महाराष्ट्र शासन

सहपत्र : वरीलप्रमाणे.

भारत सरकार
स्वास्थ्य सेवा महानिदेशालय,
स्वास्थ्य एवं परिवार कल्याण मंत्रालय



सत्यमेव जयते
CDSCO

केन्द्रीय औषध मानक नियन्त्रण संगठन
पश्चिम सण्ड
उप औषध नियंत्रक (भारत) का कार्यालय
चौथा तल, झोनल एफ.डी.ए. भवन,
जी.एम.एस.डी.कम्पाउंड, बिलासीस रोड,
मुम्बई सेन्ट्रल, मुम्बई-४०० ००८.

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GOVERNMENT OF INDIA
Ministry of Health and Family Welfare
Directorate General of Health Services

CENTRAL DRUGS STANDARD CONTROL ORGANISATION
WEST ZONE

Office of the Deputy Drugs Controller (India)
4th Floor, Zonal FDA Bhawan, GMSD Compound, Bellasis Rd,
Mumbai Central, Mumbai-400 008.
Tel: 022 - 23002279 / 23002215
Fax : 022-23002271
Email: wzmumbai@cdsco.nic.in

Ref. No. 5/Investigation/WZ-2019/ 2274, 2275

March 15, 2019

20 MAR 2019

To
The Drugs Controller General (India)
CDSCO (HQ), FDA Bhawan,
Kotla Rd.,
New Delhi 110 002

Kind Attn: Enforcement Division, CDSCO (HQ)

Subject: Forwarding of Joint Investigation report of the investigation carried out at M/s Maruti Nursing Home, 1st flr., Ginnar Sociey, Hanuman Chowk, Gokhale Rd., Mulund, (E) Mumbai 40 0081 in connection with the complaint regarding death of Smt. Kamini Barkur w/o Sh. Umeshchandra Barkur by sub-standard drug Rokfos, Mfd by: CIPLA Limited reg.

Sir,


This is with reference to the CDSCO (HQ) email dtd. 23/10/2018 and 13/11/2018 on the subject matter.

In this connection, joint investigation at M/s Maruti Nursing Home, Mulund, Mumbai was carried out 29/01/2019 and 01/02/2019 by Shri. Popat D Thorat, Drugs Inspector, CDSCO WZ, Mumbai along with Sh. Sanjay Rathod, Drugs inspector, FDA, Gr. Mumbai, Zone-4 and an expert Dr. Sudhir R Pawar, Professor & HOD Pharmacology, Lokananya Tilak Municipal Medical College & General Hospital, Mumbai in connection with the complaint regarding death of Smt. Kamini Barkur w/o Sh. Umeshchandra Barkur by sub-standard drug Rokfos, manufactured by M/s. CIPLA Limited, and also sold illegally at M/s Maruti Nursing Home, Mulund, Mumbai.

The investigation report giving observations and recommendations by the inspection team is enclosed herewith along with its supporting documents as Annexure 1 to Annexure 14 for information and further necessary action in the matter.

Encl: as above

Yours faithfully,


(Dr. P. B. N. Prasad)
Dy. Drugs Controller (India)
CDSCO (West Zone) Mumbai

Copy to: The Joint Commissioner (Gr. Mumbai), FDA Maharashtra, Mumbai 400051

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Joint-Investigation Report
of
M/s Maruti Nursing Home, 1st Floor, Girnar Society, Hanuman Chouk, Gokhale Road, Mulund (East), Mumbai-400081.

Subject-Joint investigation of M/s Maruti Nursing Home, Mulund, Mumbai in connection with the complaint regarding death of Smt. Kamini Barkur w/o Sh. Umeshchandra Barkur by sub-standard drug Rokfos, manufactured by M/s Cipla Limited and sold illegally at Maruti Nursing Home, Mulund

On the basis of instructions received from the DDC(I), CDSCO (WZ), Mumbai vide letter no. 5/Complaint Investigation/WZ-2019/945 dated 29/01/2019, the undersigned offices visited the premises of **M/s Maruti Nursing Home, Shop No. 1 & 1st Floor, Girnar Society, Hanuman Chouk, Gokhale Road, Mulund (East), Mumbai-400081** to investigate the subject matter cited above. Investigating team also collected documents from FDA, Maharashtra, Bandra office w.r.t. inspections performed and action taken by the FDA Maharashtra in the subject matter.

Date of Investigation: 29/01/2019 & 01/02/2019

Purpose of Investigation:

To investigate the matter w.r.t. complaint made by Shri. Umeshchandra Barkur regarding death of Smt. Kamini Barkur w/o Sh. Umeshchandra Barkur by sub-standard drug Rokfos, manufactured by M/s Cipla Limited and sold illegally at M/s Maruti Nursing Home, Mulund

Details of site visited:-

M/s Maruti Nursing Home, 1st Floor, Girnar Society, Hanuman Chouk, Gokhale Road, Mulund (East), Mumbai-400081 is registered hospital.

Investigating team also collected documents from FDA, Maharashtra, Bandra office w.r.t. inspections performed and action taken by the FDA Maharashtra in the subject matter.

Investigation team Members

- 1. Dr. Sudhir RPawar, Professor and Head Dept. of Pharmacology, Lokmanya Tilak Municipal Medical College & General Hospital, Mumbai (Expert).
- 2. Mr. P.D. Thorat, Drugs Inspector, Central Drugs Standard Control Organization (West-Zone), Mumbai
- 3. Mr. Sanjay Rathod, Drugs Inspector, FDA Maharashtra, Greater Mumbai, Zone-4

Firm's representative Present During investigation:

Dr. Mihiegiri I. Goswami, Proprietor, M/s Maruti Nursing Home, Shop No. 1 & 1st Floor, Girnar Society, Hanuman Chouk, Gokhale Road, Mulund (East), Mumbai-400081 was present during the investigation.

Background

Complaint dated 23rd July 2018 made by Shri. Umeshchandra Barkur to CDSC, WZ, Mumbai regarding death of his wife (Late Smt. Kamini Barkur) from serious adverse drug reactions of sub-standard drug IV Rokfos, manufactured by M/s Cipla Limited and administered at Maruti Nursing Home, Mulund to Smt. Kamini Barkur.

Investigation findings

Observations noticed during the investigation are summarized below.

Documents verified.

Investigating officers were verified the in patient record file of Late Smt. Kamini Barkur available at M/s Maruti Nursing Home, Mulund and pathological test reports of Late Smt. Kamini Barkur during her hospitalization at M/s Maruti Nursing Home, Mulund from 09.06.2014 to 14.06.2014. Investigating team also collected documents from FDA, Maharashtra, Bandra office w.r.t. inspections performed and action taken by the FDA Maharashtra in the subject matter.

Summarized observations-

On the basis of discussions made with the Dr. Mihiegiri I. Goswami, and documents verified at M/s Maruti Nursing Home, Mulund and Documents collected from FDA, Bandra Mumbai, following observations were made.

1. Smt. Kamini Barkur w/o Sh. Umeshchandra Barkur was hospitalized in M/s Maruti Nursing Home, 1st Floor, Girnar Society, Hanuman Chouk, Gokhale Road, Mulund (East), Mumbai-400081 on 09/06/2014 with provisional diagnosis of **Cervical-Spondylitis & Stiff Neck**.
(Ref annexure 1 for copy of in patient record file).
2. Complainant in written complaint dated 23/07/2018 made to DDC(I), WZ, Mumbai has submitted photograph of carton of drug **Rokfos produced by treating doctor in patient record of her wife**.
Details of drug as specified in photograph of carton are as below
Name of Drug: Rokfos (Zoledronic Acid Solution for Infusion 5mg/100ml)
Batch No. V40056,
Mfg. FEB.14
Exp. Jan.16
As per available information on carton expiry date of drug was **Jan.16 and drug was administered to Smt. Kamini Barkur on 09/06/2014**.
(Ref annexure 2 for photograph of carton of drug Rokfos submitted by complainant).
3. On prescription dated 09/06/2014 single dose of drug Zoledronic Acid IV (Zobone IV) was prescribed to Smt. Kamini Barkur. Dr. Mihiegiri I. Goswami stated that single dose of drug Zoledronic Acid IV (Rokfos IV) was administered to her on 09/06/2014.
(Ref annexure 3 for copy of prescription dated 09/06/2014).
4. M/s Maruti Nursing Home, has submitted purchase invoice No. 00788 dated 25/04/2014 received from AMI Agency, Shop No. #2, Pavwala Chawl, Ganesh Maidan, Sainath Nagar, Ghatkopar (W), Mumbai-26 for purchase of drug **ROKPOS IV, Batch No. V40056, Quantity Purchased-5 Units**.

(Ref annexure 4 for copy of purchase invoice No. 00788 dated 25/04/2014 submitted by M/s Maruti Nursing Home).

5. As per available records with hospital i.e. patient file it was observed that only single dose of drug Zoledronic Acid, IV was administered to Smt. Kamini Barkur on 09/06/2014 and said drug was not administered to her again during her hospitalization at M/s Maruti Nursing Home till 14/06/2014.

6. As per available records Smt. Kamini Barkur was discharged from M/s Maruti Nursing Home on 14/06/18. It was explained by Dr. Mihiegiri I. Goswami that she was shifted to Platinum Hospital, G-103, D.D. Upadhya Marg, Mulund for further treatment.

7. Complainant made complaint dated 28th Apr 2015 to Joint Commissioner FDA, Maharashtra that drugs are sold above MRP at M/s Maruti Nursing Home (Ref annexure 5 for copy of complaint).

8. In view of complaint dated 28th Apr 2015 made by Shri. Umeshchandra Barkur, officials from FDA Maharashtra raided the premises of M/s Maruti Nursing Home on 22/07/2015 along with two witnesses. It was observed that hospital is involved in sale of drugs without holding requisite license as per the provisions of Drugs and Cosmetics Act, 1940.

(Ref annexure 6 for detailed investigation report).

9. Drugs Inspector, FDA Maharashtra, has filed a case against Dr. Mihiegiri I. Goswami, Proprietor M/s Maruti Nursing Home, Shop No. 1 & 1st Floor, Girnar Society, Hanuman Chouk, Gokhale Road, Mulund (East), Mumbai-400081 and Smt. Ashwini Kallapa Kamble Receptionist cum salesman at M/s Maruti Nursing Home, Shop No. 1 & 1st Floor, Girnar Society, Hanuman Chouk, Gokhale Road, Mulund (East), Mumbai-400081 in the court of Hon'ble Metropolitan Magistrate's, 15th, Mazgaon Court, At Sewree, Mumbai for contravention of section 18(c), Section 18-A and section 22(1)(cca) of Drugs and Cosmetics Act, 1940.

(Ref annexure 7 for copy of complaint filed by drugs inspector in the court of Hon'ble Metropolitan Magistrate's, 15th, Mazgaon Court, At Sewree, Mumbai).

10. Said case is under court of law and matter is **sub-judice**.

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11. Complainant made complainant dated 14th May 2018 to Joint Commissioner FDA, Greater Mumbai Division, Maharashtra w.r.t death of his wife from serious adverse drug reactions of injection IV Rokfos Manufactured by Cipla Ltd.

Ref annexure 8 for copy of complaint

12. To investigate the subject matter officials from FDA Maharashtra, visited premises of M/s Novacare Drugs Specialties Pvt. Ltd., 14 & 15, Vardhaman Complex, L.B.S. Marg, Fitwell Compound, Vikhroli (W), Mumbai-400 083 on 24/05/2018.

Ref annexure 9 for copy of inspection report.

13. Stock of drug Rokfos Injection I V B No. V4006 was not found in the premises M/s Novacare Drugs Specialties Pvt. Ltd., 14 & 15, Vardhaman Complex, L.B.S. Marg, Fitwell Compound, Vikhroli (W), Mumbai-400 083. However, stock of following batches of Rokfos Injection I V were found in the premises M/s Novacare Drugs Specialties Pvt. Ltd.,

Product Name	Batch No	Exp. Date	Available Qty.
Rokfos Injection	GI70312	AUG.19	18 X 100 ml
Rokfos Injection	GI70398	NOV.19	3 X 100 ml

Out of above two batches, drugs inspector, FDA Maharashtra had taken sample of Batch No. GI70312 under Form 17 Dated 24/05/2018 for the purpose of test and analysis.

14. The said drug sample was sent to the Government Analyst, Food and Drugs Control, Laboratory, Mumbai, Maharashtra along with Form 18 dated 24/05/2018 for analysis including test for Toxicity

Ref annexure 10 for copy of letter dated 24/05/2018 written by inspector Government Analyst, Food and Drugs Control, Laboratory, Mumbai for performing test for Toxicity.

Ref annexure 11 for copy for form 18

15. The sampled drug was declared as of Standard Quality vide Govt. Analyst, Drugs Control Laboratory vide report No. STD/MUM/106142/2018 dated 12/09/2018. Drug sample was also found meeting test for toxicity.

Ref annexure 12: Copy of Government Analysts test report in Form 13

16. It was observed that Smt. Kamini Barkur w/o Sh. Umeshchandra Barkur had hospitalized in M/s Maruti Nursing Home, Mulund, Mumbai for treatment of **Cervical-Spondylitis & Stiff Neck and it is not a case of clinical trial as defined under Rule 122-DAA of Drugs And Cosmetics.**
17. In view of inadequate information available with respect to patient history, other drugs administered & the sequence of events occurred after discharge of patient from M/s Maruti Nursing Home, Mulund, clinical investigation reports as well as the exact cause of death (Post Mortem findings, if done); it is difficult to comment on whether there was lapse in the standard of care administered. Opinion of the concerned specialty expert's i.e. Rheumatologist, Intensivists, TB - Chest specialist etc., may be sought to ascertain this.
18. In this context, Drugs Controller General, India, has already written letter vide ref No.PG/90/ADR/Rokfos/2018/DCG(I) dated 26/07/2018 to National Coordination Centre, Pharmacovigilance Programme of India, IPC, Gaziabad and requested to examine the issue under PvPI and give their opinion to take necessary action in the matter (**Ref annexure 13**).
19. ADC(I), Public Grievance Cell, CDSCO, HQ, New Delhi has also written a reminder letter vide ref No.PG/90/ADR/Rokfos/2018/DCG(I) dated 10/09/2018 to National Coordination Centre, Pharmacovigilance Programme of India, IPC, Gaziabad and requested to examine the issue under PvPI and give their opinion to take necessary action in the matter (**Ref annexure 14**).

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Remarks.

As per 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 said drug was not administered to her again during her hospitalization at M/s Maruti Nursing Home till 14/06/2014.

It is observed that the of Smt. Kamini Barkur who Sh. Umeshchandra Barkur was hospitalized in M/s Maruti Nursing Home, Mulund, Mumbai for treatment of Cervical-Spondylitis & Stiff Neck and it is not a case of clinical trial as defined under Rule 127-DAA of Drugs And Cosmetics Rules 1945.

As complaint is related to adverse drug reaction, opinion of National Coordination Centre, Pharmacovigilance Programme of India, IIC, Gazlbad may be obtained to take necessary action in the matter.

Also opinion of the concerned specialty expert's i.e. Rheumatologist, Intensivists,

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Chest specialist etc., may be sought to ascertain lapses in the standard of care administered, if any?

Dr. Sudhir R. Pawar, Professor and HOD Pharmacology, Lokmanya Tilak Municipal Medical College & General Hospital, Mumbai (Expert).

Mr Bipal Tharot
Drugs Inspector
CDSCO, WZ, Mumbai

Mr. Sanjay Rathod, Drugs Inspector, FDA Maharashtra, Greater Mumbai Zone-4

Annexure

1. Annexure 1: Copy of in Patient Record File.
2. Annexure 2: Photograph of carton of drug Rokfos submitted by complainant.
3. Annexure 3: Copy of prescription dated 09/06/2014.
4. Annexure 4: Copy of purchase invoice No. 00788 dated 25/04/2014 submitted by M/s Maruti Nursing Home.
5. Annexure 5: For copy of complaint dated 28th Apr 2015 made by complainant to Joint Commissioner FDA, Maharashtra that drugs are sold above MRP at M/s Maruti Nursing Home.
6. Annexure 6: Detailed investigation report dated 22/07/2015 for investigation performed by officials from FDA Maharashtra at the premises of M/s Maruti Nursing Home
7. Annexure 7: Copy of complaint filed by drugs inspector, FDA Maharashtra against Dr. Mihiegiri I. Goswami, Proprietor M/s Maruti Nursing Home and Smt. Ashwini Kallapa Kambhcn in the court of Hon'ble Metropolitan Magistrate's, 15th, Mazgaon Court, At Sewree, Mumbai.
8. Annexure 8: For copy of complaint dated 14th May 2018 made by complainant to Joint Commissioner FDA, Maharashtra w.r.t death of his wife from serious adverse drug reactions of injection IV Rokfos Manufactured by Cipla Ltd.
9. Annexure 9: For copy of inspection report of M/s Novacare Drugs Specialties Pvt. Ltd., 14 & 15, Vardhaman Complex, L.B.S. Marg, Fitwell Compound, Vikhroli (W), Mumbai-400 083 performed on 24/05/2018.
10. Ref annexure 11: For copy of letter dated 24/05/2018 written by inspector to Government Analyst, Food and Drugs Control, Laboratory, Mumbai for performing test for Toxicity.
11. Annexure 10: For copy of Form 18.
12. Annexure 12: Copy of Government Analysts test report in Form 13.
13. Annexure 13: Copy of letter vide ref No.No.PG/90/ADR/Rokfos/2018/DCG(I) dated 26/07/2018 written by Drugs Controller General, India, to National Coordination Centre, Pharmacovigilance Programme of India, IPC.

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14. Annexure 14: Copy of reminder letter vide ref No.PG/90/ADR/Rokfos/2018/DCG(I) dated 26/07/2018 written by ADC(I),Public Grievance Cell, CDSCO,HQ, New to National Coordination Centre, Pharmacovigilance Programme of India, IPC, Gaziabad.