

GOVERNMENT OF RAJASTHAN
DRUGS CONTROL ORGANISATION, SWASTHYA BHAVAN, TILAK MARG
JAIPUR

No./DC/D-I/Amend-41/2010/484

Dated 18.11.2010

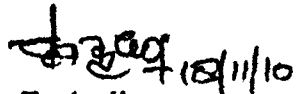
- 1- Mission Director, NRHM, Medical & Health Services, Hqr. Jaipur.
- 2- Project Director, RHSDP, Medical & Health Services, Hqr. Jaipur
- 3- Director Medical & Health Services(PH/FW/MSU/ESI/AIDS) Raj. Jaipur
- 4- All Pricipals, Medical Colleges, Rajasthan
- 5- All Superintendent., Associated Group of Hospitals, Rajasthan.
- 6- Secretary, Store Purchase Organisation, Hqrs.
- 7- All Asstt. Drugs Controllers, Rajasthan
- 8- All Drug Control Officers, Rajasthan
- 9- All Manufacturers of Rajasthan State.

Subject:- Prohibition (Ban) of manufacture, sale & distribution of "Rosiglitazone and its formulations for Human use" under section 26-A of Drugs & Cosmetics Act, 1940- regarding.

Ref:- Letter No. F.No. 12-01/2010-DC(PT-18) Dt. 16-11-2010 with copy of Gazette of India Notification No. G.S.R.910(E) Dt. 12-11-2010 issued by Ministry of Health & F.W. (Department of Health & Family Welfare) New Delhi.

The Govt. of India, Ministry of Health & Family Welfare, New Delhi has published refered notification on the subject issue (copy of which is enclosed) thereby prohibiting the manufacture, Sale & distribution of "Rosiglitazone and its formulations for Human use" with immediate effect. This is in continuation of earlier communication of this office vide No. DC-2/A-1/2010/1478 Dt. 13-10-2010 Hence, it is enjoined upon all to ensure the Compliance in totality i.e. to desist from manufacture, sale and distribution of "Rosiglitazone and its formulations for Human use" with immediate effect & as advised by Drugs Controller General (India) New Delhi; the Chemists & Druggists be directed to stop the sale and distribution of these formulations with immediate effect & to return the unused stocks to the manufacturers though dealers/distributors.


Encl: Copy of letter dt. 16-11-2010 & G.S.R. 910(E) dt. 12-11-2010


Drugs Controller
Rajasthan, Jaipur

484
18.11.2010

Copy Forwarded to following for information & needful action to:-

- 1- Drugs Controller General (India), F.D.A. Bhawan, Kotla Road, New Delhi. in referance to his referred letter.
- 2- Dy. Secretary to Govt., Medical & Health (Gr.II) Deptt. Raj. Jaipur
- 3- Dy. Drugs Controller (I), CDSCO(NZ), Kamla Nehru Nagar, Hapur Road, Ghaziabad, U.P.
- 4- Drugs Controller-II, Raj. Jaipur
- 5- All P.M.Os/ C.M.&H.Os, Rajasthan State
- 6- Public Relation Officer, Swasthya Bhawan, Tilak Marg, Jaipur to please get published in all leading news papers.
- 7- President, RPMA, SP-2, 22-Godam, Jaipur to inform all manufacturers for compliance.
- 8- President, Rajasthan Chemist Association, Dawa Bazar, Film Colony, Chaura Rasta, Jaipur to please ask all the Chemists to restrain from distribution & sale of above banned product and return it back to manufacturer.
- 9- Secretary, Jaipur Medical Association, S.M.S. Hospital Campus, Jaipur
- 10- Computer Desk/Concerning files
- 12- Server Room I/c, Pl. Put the Order on deptt. website put


Drugs Controller
Rajasthan, Jaipur

18/11/10

18/11/2010

3609
18-11-10

18/11/10

F.No. 12-01/2010-DC(PT-18)

The Drugs Controller General, (India)
Directorate General of Health Services
FDA Bhawan, Kotla Road, New Delhi

Adc (Shin Deaf)
Procten

Dt. 16.11.2010

To,

Urgent
Top Priority
Banned
under 26 A

18/11/2010
DGD-I

All State Drug Controllers

Sub: Prohibition to manufacture for sale and distribution and sale of Rosiglitazone and its formulations with immediate effect under Section 26A of the Drugs and Cosmetic Act, 1940 in the country under Gazette notification GSR 910 (E) dated 12.11.2010-regarding.

Sir,

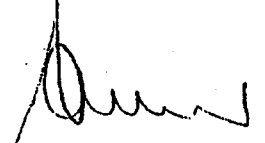
The Government of India, Ministry of Health and Family Welfare has published a Gazette Notification GSR 910(E) dated 12.11.2010, in exercise of powers conferred under Section 26A of the Drugs and Cosmetics Act prohibiting the manufacture for sale, and sale of the drug Rosiglitazone and its formulations for human use with immediate effect in the country.

A copy of the said Notification is enclosed for your information and necessary action in the matter.

As the manufacture and sale of Rosiglitazone stands prohibited with immediate effect, it is requested that you may kindly ensure that the manufacturers licenced to manufacture the drug formulations containing Rosiglitazone in your State stop manufacturing these formulations with immediate effect and make arrangement to recall the formulations from the market. The chemists and Druggists in your State should also be directed to stop the sale of these formulations with immediate effect and return the unused stocks to the manufacturers.

The action taken by you in the matter may please be communicated to this Directorate.

Yours faithfully,



(Dr. Surinder Singh)
Drugs Controller General (India)

Copy forwarded for information and necessary action to all Zonal /sub zonal offices of CDSCO with request for necessary follow up with the State Drugs Control Authorities and ensure that the sale of Rosiglitazone and its formulations it stopped with immediate effect by the manufacturers as well as Chemists and Druggists.

(Dr. Surinder Singh)
Drugs Controller General (India)



भारत का राजपत्र

The Gazette of India

असाधारण

EXTRAORDINARY

भाग II—खण्ड 3—उप-खण्ड (1)
PART II—Section 3—Sub-section (1)
प्राधिकार से प्रकाशित
PUBLISHED BY AUTHORITY

No. 628]

नई दिल्ली, शुक्रवार, नवम्बर 12, 2010/कार्तिक 21, 1932

No. 628]

NEW DELHI, FRIDAY, NOVEMBER 12, 2010/KARTIKA 21, 1932

स्वास्थ्य और परिवार कल्याण मंत्रालय
(स्वास्थ्य और परिवार कल्याण विभाग)

अधिसूचना

नई दिल्ली, 12 नवम्बर, 2010

सा.का.नि. 910(अ).—केंद्र सरकार इस बात से संतुष्ट है कि रोजिग्लिटैजोन युक्त औषध फार्मूलेशनों के इस्तेमाल से मानव के लिए कुछ जोखिम शामिल होने की संभावना है;

और औषध के अधिक सुरक्षित विकल्प उपलब्ध हैं;

और केंद्र सरकार इस बात से संतुष्ट है कि जनहित में इस औषध के विनिर्माण, बिक्री और वितरण को प्रतिबंधित करना आवश्यक और उचित है।

इसलिए अब औषध और प्रसाधन सामग्री अधिनियम, 1940 (1940 का 23) की धारा 26-क द्वारा प्रदत्त शक्तियों का प्रयोग करते हुए केंद्र सरकार एतद्वारा निम्नलिखित औषध के विनिर्माण, बिक्री और वितरण को तत्काल प्रभाव से प्रतिबंधित करती है, अर्थात् :-

"मानव इस्तेमाल के लिए रोजिग्लिटैजोन और इसके 'फार्मूलेशन"

[फा. सं. X 11014/5/2010-डीएफक्यूसी]

डॉ. ए. के. पण्डा, संयुक्त सचिव

MINISTRY OF HEALTH AND FAMILY WELFARE
(Department of Health and Family Welfare)

NOTIFICATION

New Delhi, the 12th November, 2010

G.S.R. 910(E).—Whereas the Central Government is satisfied that use of drug formulations containing Rosiglitazone are likely to involve certain risk to human beings;

And whereas safer alternatives to the drug are available;

And whereas the Central Government is satisfied that it is necessary and expedient to prohibit the manufacture, sale and distribution of this drug in public interest.

Now, therefore, in exercise of powers conferred by Section 26-A of the Drugs and Cosmetics Act, 1940 (23 of 1940), the Central Government hereby prohibits the manufacture, sale and distribution of the following drug, with immediate effect, namely:—

"Rosiglitazone and its formulations for human use".

[F.No. X 11014/5/2010-DFQC]

Dr. A. K. PANDA, Jt. Secy.