

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

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

Dt. 16.11.2010

To,

- 1. Drug Manufacturers Associations**
- 2. All India Organization of Chemists and Druggists, Mumbai.**

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.

It is requested that wide publicity may be given to the content of the Notification to your members through the Journals of your associations and sisters associations for the information of the members for the purpose of compliance to the Notification.

Yours faithfully,



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

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

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

Dt. 16.11.2010

To,

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

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असाधारण

EXTRAORDINARY

भाग II—खण्ड 3—उप-खण्ड (i)

PART II—Section 3—Sub-section (i)

प्राधिकार से प्रकाशित

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

स्वास्थ्य और परिवार कल्याण मंत्रालय

MINISTRY OF HEALTH AND FAMILY WELFARE

(स्वास्थ्य और परिवार कल्याण विभाग)

(Department of Health and Family Welfare)

अधिसूचना

NOTIFICATION

नई दिल्ली, 12 नवम्बर, 2010

New Delhi, the 12th November, 2010

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

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;

और औषध के अधिक सुरक्षित विकल्प उपलब्ध हैं;

And whereas safer alternatives to the drug are available;

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

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.

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

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:—

“मानव इस्तेमाल के लिए रोजिग्लिटेजोन और इसके फार्मूलेशन”

“Rosiglitazone and its formulations for human use”.

[फा. सं. X 11014/5/2010-डीएफव्यूसी]

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

डॉ. ए. के. पण्डा, संयुक्त सचिव

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