

धूम्रपान का वर्तमान या पूर्व वृत्तांत, कुछ व्यावसायिक या कीमोथेरेपी एजेंट्स जैसे साइक्लोफोस्फमाइड से संपर्क, या श्रोणीय क्षेत्र का पूर्व उन्मूलन।

- वृद्ध रोगियों में उपचार से पहले और उपचार के दौरान उपयोग पर ध्यानपूर्वक विचार किया जाए क्योंकि आयु के साथ मूत्राशय कैंसर का जोखिम बढ़ जाता है। वृद्ध रोगियों का उपचार न्यूनतम संभावित खुराक के साथ शुरू किया जाना चाहिए और नियमित रूप से निगरानी की जानी चाहिए क्योंकि पायोलिटाजोन के साथ मूत्राशय कैंसर और हृदय आघात का जोखिम जुड़ा हुआ है।

[फा. सं. 4-01/2011-डीसी/पिओग्ल]

अरुण के. पंडा, संयुक्त सचिव

MINISTRY OF HEALTH AND FAMILY WELFARE

(Department of Health and Family Welfare)

NOTIFICATION

New Delhi, the 31st July, 2013

**G.S.R. 520(E).**—Whereas the Central Government was satisfied that the use of the drug Pioglitazone and all drug formulations containing Pioglitazone was likely to involve risk to human beings and whereas safer alternatives to the said drug are available;

Whereas, the Central Government was satisfied that it was necessary and expedient to regulate by way of suspension, the manufacture for sale, sale and distribution of the said drug in the country in public interest, and accordingly in exercise of the powers conferred by section 26A of the Drugs and Cosmetic Act, 1940 (23 of 1940), the Central Government suspended the manufacture for sale, sale and distribution of Pioglitazone and all formulations containing Pioglitazone for human use through the notification number G.S.R. 379 (E) dated 18<sup>th</sup> June, 2013;

Whereas, the Drugs Technical Advisory Board has examined the issue of suspension of manufacture and sale of the said drug on 19<sup>th</sup> July, 2013 and has recommended that the suspension of the drug should be revoked and allowed to be marketed subject to certain conditions the manufacturers shall mention on their package insert and promotional literature of the drug;

Now, therefore, on the basis of the recommendations of the Drugs Technical Advisory Board, the Central Government hereby revokes the notification G.S.R. 379(E) dated 18<sup>th</sup> June, 2013 subject to the following conditions as recommended by the Drugs Technical Advisory Board:-

"Pioglitazone and all formulations containing Pioglitazone for human use is allowed to be manufactured for sale, sale and distribution subject to the condition that the manufacturers shall mention the following on their package insert and promotional literature of the drug;

1. The drug should not be used as first line of therapy for diabetes.
2. The manufacturer should clearly mention following box warning in bold red letters.

Advice for healthcare professionals:

- Patients with active bladder cancer or with a history of bladder cancer, and those with uninvestigated haematuria, should not receive pioglitazone
- Prescribers should review the safety and efficacy of pioglitazone in individuals after 3-6 months of treatment to ensure that only patients who are deriving benefit continue to be treated. Pioglitazone should be stopped in patients who do not respond adequately to treatment (eg, reduction in glycosylated haemoglobin, HbA1c)
- Before starting pioglitazone, the following known risk factors for development of bladder cancer should be assessed in individuals: age, current or past history of smoking, exposure to some occupational or chemotherapy agents such as cyclophosphamide, or previous irradiation of the pelvic region
- Use in elderly patients should be considered carefully before and during treatment because the risk of bladder cancer increases with age. Elderly patients should start on the lowest possible dose and be regularly monitored because of the risks of bladder cancer and heart failure associated with pioglitazone."

[F. No. 4-01/2011-DC/Piog]

ARUN K. PANDA, Jt. Secy.

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

No. DC/D-1/Amend-41/2013/ 359

Dated: 02/8/2013

Copy forwarded for information and necessary action to:-

1. Drugs Controller General (India) FDA Bhawan, Kotla Road, New Delhi.
2. Mission Director, NRHM, Medical & Health Services, Jaipur.
3. Managing Director, RMSCL, Swasthya Bhawan, Jaipur.
4. Dy. Secretary to Govt., Medical & Health (Gr.II) Deptt. Rajasthan, Jaipur.
5. Dy. Drugs Controller (I) CDSCO (NZ), Kamla Nehru Nagar, Hapur Road, Ghaziabad.
6. Director, Medical & Health Services, (PH/FW/MSU/ESI/Aids), Jaipur.
7. Drugs Controller-I, Rajasthan, Jaipur.
8. All Principals, Medical Colleges, Rajasthan State.
9. All Superintendent, Associated Group of Hospitals, Rajasthan State.
10. All PMO's/ CMHO's, Rajasthan State.
11. All Asstt. Drugs Controllers, Rajasthan State.
12. Asstt. Drugs Controller (SDEC) Hqr.
13. All Drug Control Officers, Rajasthan State.
14. Dy. Director, Drug Testing Laboratory, Sethi Colony, Jaipur.
15. President, Raj. Pharm. Manufacturers Association, SP-2, 22 Godam Indl. Estate, Jaipur.
16. All Pharmaceutical Manufacturers, Rajasthan State.
17. President Rajasthan Chemist Association, Dawa Bazar, Film Colony, Chaura Rasta, Jaipur.
18. Director, Public Relations, Sachivalaya, Jaipur for publicity of said order.
19. Public Relation Officer, Swasthya Bhawan, Tilak Marg, Jaipur to please get it published in all leading newspapers.
20. Incharge, Server Room with request to upload this letter on Departmental website, under Gazette of India, and also to please e-mail to All PMO's, C.M.&H.O.'s & Asstt. Drugs Controllers, Rajasthan State.
21. C-desk/ Guard file.

(V.K. Dhal)

Drugs Controller,  
Rajasthan, Jaipur.