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Suspension of anti-diabetes drug pioglitazone may be withdrawn

Instead, there could be labels cautioning patients about the drug's side effects

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New Delhi, 14 July

The government was planning to revoke the recent suspension of marketing of anti-diabetic drug pioglitazone, sources said. Instead of a blanket ban, there could be a boxed warning on the packaging of the drug, cautioning patients about its possible side effects, they added.

Major pharma companies like Sun Pharma, Lupin and Abbott sell pioglitazone in India, an estimated market of around ₹700 crore annually.

Following opposition from the industry as well as medical fraternity, the government called for a review meeting on July 11. The meeting, which was chaired by the Director General Health Services and Drug Controller General of India, was attended by many prominent diabetologists and pharmacologists from across the country. According to an official source, the decision to consider carrying a boxed warning on the drug instead of banning the medicine completely was taken after receiving



RISKY MEDICINE

- The sale of pioglitazone in the country was recently suspended, after seven cases of the drug causing potential risk of bladder cancer were reported in Chennai
- Major pharma companies such as Sun Pharma, Lupin and Abbott sell the drug in India, used by around 3-4 million patients in India, with an estimated market of around ₹700 crore annually
- The drug is banned in France; in the US and the UK the medicine is sold with a warning on the packet

comments from medical and clinical experts in the meeting.

"There were 12 experts who were called for the meeting and were asked for their comments about the drug. Almost everyone supported the need of the drug for the patients and came with the suggestion that there should certainly be a boxed warning on the packaging of the medicine," said the official. He added

the suggestion will now be presented to the Drug Technical Advisory Board (DTAB) for consideration.

The Board is scheduled to meet on July 19, when the industry is also expected to present its case in favour of the drug supported by scientific data and facts.

If the proposal is cleared by the DTAB, the government will revoke the suspension order on the sale of

the drug and ask companies to carry the warning.

The government had recently suspended the sale of pioglitazone in India after around seven cases of adverse effects of the drug causing potential risk of bladder cancer were reported in Chennai.

However, there are no other such cases reported in India. The drug, which is used by 3-4 million patients in India, is banned in France. However, in countries such as the US and the UK, the medicine is sold with a boxed warning on the label.

"Step towards lifting the ban on Pioglitazone is a welcome and progressive. When that is firmly in place, the next, and most important, step will be to educate physicians about possible restrictions of its use, and inform patients about its adverse effects before initiating it," said Dr Anoop Misra of Fortis C-Doc Centre of Internal Medicine.

The review meeting was attended by doctors from institutes such as Fortis, All India Institute of Medical Sciences, Lok Nayak Jai Prakash Hospital and Guru Tek Bahadur Medical College.