



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Press Office

Press release

European Medicines Agency clarifies opinion on pioglitazone and the risk of bladder cancer

Positive benefit-risk balance confirmed as second and third line treatment

The European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) has clarified its opinion on pioglitazone-containing anti-diabetes medicines and the risk of bladder cancer on the request of the European Commission. The Committee confirmed its previous opinion, introducing some clarifications in terms of transparency towards patients and health care professionals. Pioglitazone remains a valid treatment option for certain patients with type 2 diabetes, but only when certain other treatments (metformin) have not been suitable or have failed to work adequately.

The new warnings and contraindications recommended in July 2011 remain in place.

In July 2011 the CHMP had finalised a review of pioglitazone and the risk of bladder cancer. The Committee found that there was a small increased risk of bladder cancer. However, because the Committee considered that there are a limited number of patients who cannot be adequately treated by other treatments, the Committee concluded that pioglitazone should remain available as a treatment option, but that prescribers should carefully select patients and monitor their response to treatment. The latest amendments make it clearer for doctors and patients that pioglitazone remains a valid treatment option for certain patients with type 2 diabetes, but only when certain other treatments (metformin) have not been suitable or have failed to work adequately.

The updated opinion will be sent to the European Commission for the adoption of a decision.

Notes

1. This press release, together with all related documents, is available on the Agency's website.
2. More information on the July 2011 review is available on the Agency's website.
3. This press release corrects the press release issued on 21 October 2011.
4. More information on the work of the European Medicines Agency can be found on its website: www.ema.europa.eu



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