



Conclusions of European Medicines Authority Safety Review of Pioglitazone Welcomed by Association of British Clinical Diabetologists

The European Medicines Agency (EMA) has reviewed safety data for the blood glucose lowering agent pioglitazone in the light of reports of increased rates of bladder cancer. The decision has been made to continue the availability of this pharmaceutical agent although it should be withdrawn in those at risk of or with previous bladder cancer.

Pioglitazone, together with a related medication rosiglitazone, were the second generation in a group of drugs known as the thiazolidinediones. These oral agents proved valuable in the treatment of diabetes as they improve insulin sensitivity, avoiding the need for insulin injections. In individuals who responded, there was a significant lowering of the blood glucose levels which is associated with a reduction in the future risk of complications. One of the landmark trials, the PROactive study, examined the effect of treatment with pioglitazone in people with pre-existing circulatory damage due to diabetes. Over the 3 year trial period, in those treated with pioglitazone, there was a reduction in certain markers of circulatory damage. The use of these treatments, therefore, became widespread. Some years ago, however, after examination of long term research data, rosiglitazone was withdrawn from the market when studies suggested that there may be an increase in the heart attack rate in people on this treatment. Examination of the data for pioglitazone did not confirm any similar adverse effects and the licence was continued.

As part of long term surveillance studies, there have been reports of an increase in the rate of bladder cancer in pioglitazone users. The data collated by the EMA suggested that while the baseline rate of bladder cancer in people with diabetes not treated with pioglitazone was 7 in 10,000, the risk in pioglitazone users increased to 15 in 10,000. In view of the relatively small increased risk, set against the possible harm associated with withdrawal of this treatment in people who have derived benefit, the EMA have decided to continue the licence with a caution in those with or at risk of bladder cancer.

The Association of British Clinical Diabetologists (ABCD), representing senior doctors specialising in the treatment of diabetes in the UK, welcomes this decision. There was concern that withdrawal of pioglitazone, which has now been in use for many years, would increase the switching of people with diabetes to newer treatments with which we have less experience, and hence less long term safety data. Individuals on pioglitazone can be advised that the risk of bladder cancer is small, although that situation will be kept under review. Those who have any concerns are advised to contact their primary care or specialist team to discuss this. ABCD has issued guidance on treatment options in those who require a change.

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