



Primary Care Reimbursement Service  
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Mr. Denis Naughten, T.D.  
Dáil Éireann,  
Leinster House,  
Kildare Street,  
Dublin 2.

13<sup>th</sup> February, 2019

PQ: 4367/19

**To ask the Minister for Health the reason Pioglitazone remains an approved drug under the GMS for the treatment of diabetes in view of the fact that the US Food and Drug Administration has found it to be associated with bladder tumors; and if he will make a statement on the matter. -Denis Naughten.**

Dear Deputy Naughten,

The Health Service Executive has been requested to reply directly to you in the context of the above Parliamentary Question (Reference 4367/19), which you submitted to the Minister for Health for response.

The European Medicines Agency (EMA) previously published an update on the outcome of its review of pioglitazone-containing medicines and the occurrence of bladder cancer. The EMA's scientific committee, the Committee for Human Medicinal Products (CHMP), concluded that the evidence from different sources shows that there is a small increased risk of bladder cancer with pioglitazone. However, the benefit-risk balance remains positive in a limited population of type 2 diabetics. The CHMP concluded that the small increased risk could be reduced by appropriate patient selection and exclusion. Use of pioglitazone is now contraindicated in patients with current or a history of bladder cancer and in patients with uninvestigated macroscopic haematuria. The EMA has not recommended withdrawal of the product.

Yours sincerely,

Kieran Healy  
Primary Care Reimbursement Service