

R12/1074151

12



Re: Actos PI and Dear HP Letter [SEC=UNCLASSIFIED]

Bronwen Harvey to [REDACTED]
Cc: Jane.Cook, Neil.Mitchell, Nick.Simpson

22/06/2011 02:10 PM

Thank you for your draft PI changes and the draft dear HP letter.

In relation to the PI:

- We accept your proposal to remove reference to the French cohort data, on the basis that this has not yet been fully evaluated, noting that we may require further PI changes once the evaluation is completed.
- We accept the your proposal to remove the reference to consistency of clinical data with pre-clinical findings, noting that the pre-clinical information is still retained elsewhere in the PI.
- We agree with the proposed clarification for the epidemiological data paragraph that the data comes from the Kaiser Permanente Northern California (KPNC) study ie the move of the indicated paragraph to the Kaiser data description.
- We do not agree with the proposed text in relation to the recommendation that clinicians take the risk of bladder cancer into consideration when using pioglitazone. We note that your proposal is consistent with the FDA announcement but consider that the data indicate increased risk in a broader population than those with a history of bladder cancer. We consider that the text should more clearly reflect this risk and propose the following:

*Pioglitazone should not be used in patients with bladder cancer or a history of bladder cancer.
The risk of bladder cancer should be considered in the care of all patients treated with pioglitazone.*

In relation to the Dear HP letter

No changes required other than to update the text discussed above. We would appreciate seeing the final letter before it goes out.

We are working on a TGA statement to go up on our website at the same time as the HP letters are sent out and will send you the proposed text once it is ready.

Bronwen

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20/06/2011 01:51:29 PM



20/06/2011 01:50 PM

To Bronwen.Harvey [REDACTED]
cc Jane.Cook [REDACTED] Neil.Mitchell [REDACTED]
Nick.Simpson [REDACTED]
Subject Actos PI and Dear HP Letter

Dear Dr Harvey

As per your letter of Friday 17th June 2011, please find attached a draft PI and Dear HP letter incorporating information on Actos and the potential risk of bladder cancer. In addition, Eli Lilly global and Takeda have provided a response document outlining their rationale where the PI update

differs from that requested. A formal SRN will be submitted to the Office of Market Authorisation once all of the changes have been agreed.

With respect to the Dear HP letter, we have included a place holder for describing the actual PI language once this has been agreed between Lilly and TGA. Similarly, we have a placeholder for describing the overseas regulatory status and this will be added at the end of the week once the outcome of the CHMP meeting is known. The letter has been drafted this way to ensure that the overseas information will be current at the time of mail out.

(See attached file: Australia_Response Document.docx) (See attached file: ACTOS PI_v3.1_20Jun11.docx) (See attached file: DHCPL_for_Australia.docx)

Kind Regards

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[attachment "Australia_Response Document.docx" deleted by Bronwen Harvey/TGA/Health] [attachment "ACTOS PI_v3.1_20Jun11.docx" deleted by Bronwen Harvey/TGA/Health] [attachment "DHCPL_for_Australia.docx" deleted by Bronwen Harvey/TGA/Health] [attachment "pic29876.jpg" deleted by Bronwen Harvey/TGA/Health]