



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

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

23/06/2011 03:02 PM

[REDACTED]
You will need a letter from TGA indicating that we have agreed the changes that you will need to attach to your SRN.

Can you give me a contact number and I will phone you to discuss.

Bronwen

Dr Bronwen Harvey
Head, Signal Investigation Unit
Office of Product Review
Therapeutic Goods Administration
Phone: 02 6232 8071
Mobile: 0423 026 409
Email: bronwen.harvey@tga.gov.au

23/06/2011 01:05:01 PM



23/06/2011 01:04 PM

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

Dear Bronwen

Please find attached an updated version of the Actos PI incorporating the updates agreed as per your message below. The changes will also be submitted as a SRN today. At the recent BPR seminar, it was stated that a SRN required prior approval before the changes could be implemented, can you clarify whether the updated PI can be implemented based on the date of the notification or whether we must wait for an acknowledgement letter from the TGA before issuing the updated PI?

(See attached file: ACTOS PI_v3.2_23Jun11.docx)

With regard to the Dear HP letter, I have added in the PI changes and drafted a summary of the overseas regulatory situation. I have received advice this morning that the EMA will most likely issue a press release Friday morning EU time which may change this section of the letter. We propose to finalise the letter on Monday morning to ensure that the information is up to date. I have also added a statement that the PI can be downloaded from the TGA website, is this acceptable (I will ensure that the updated document is available on TGA website before the letter is distributed)?

(See attached file: DHCPL_for_Australia 23Jun11.docx)

Kind Regards
[REDACTED]

(Embedded image moved to file: pic06923.jpg)

Bronwen.Harvey [REDACTED]

22/06/2011 02:10
PM

To

cc

Jane.Cook [REDACTED]
Neil.Mitchell [REDACTED]
Nick.Simpson [REDACTED]

Subject

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

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

Dr Bronwen Harvey
Head, Signal Investigation Unit
Office of Product Review
Therapeutic Goods Administration
Phone: 02 6232 8071
Mobile: 0423 026 409

Email: bronwen.harvey [REDACTED]

20/06/2011 01:50 PM

Bronwen.Harvey [REDACTED]

To

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

[REDACTED]
(Embedded image moved to file: pic29876.jpg)
[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]

"Important: This transmission is intended only for the use of the addressee and may contain confidential or legally privileged information and has been sent in accordance with the TGA security policy.

If you are not the intended recipient, you are notified that any use or dissemination of this communication is strictly prohibited. If you receive this transmission in error please notify the author Immediately and delete all copies of this transmission."

[attachment "ACTOS PI_v3.2_23Jun11.docx" deleted by Bronwen Harvey/TGA/Health] [attachment "DHCPL_for_Australia 23Jun11.docx" deleted by Bronwen Harvey/TGA/Health] [attachment "pic06923.jpg" deleted by Bronwen Harvey/TGA/Health]