Senate Community Affairs Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2010-11, 20 October 2010

Question: E10-120

OUTCOME 1: Population Health

Topic: AVANDIA

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Senator Xenophon asked:

a) Is the Australian warning on Avandia as thorough as the warnings in the US and Europe?
b) Are Australian restrictions that apply to the marketing and prescription of Avandia equivalent to or as rigorous as those in Europe and the US?

Answer:

Warnings about the side effects of a medicine and restrictions that apply to its marketing are included in the Australian Product Information (PI) document. The PI document for Avandia is kept under review as new information becomes available.

An advisory statement was posted on the 24 September 2010 on the TGA's website in the following terms:

> The TGA is aware of recent regulatory decisions by the European Medicines Agency (EMA) and the US Food and Drug Administration (FDA) regarding the status of rosglitazone (Avandia and Avandamet).
>
> The TGA has already taken a number of significant steps to restrict the use of rosiglitazone and to preclude its use in patients at increased risk of adverse events, and the Australian approved Product Information (PI) in Australia is already more restrictive than in many overseas markets.
>
> A Boxed Warning in the approved PI document states that rosiglitazone should not be used in patients with known ischaemic heart disease. The PI also clearly lists a number of important contraindications which include use in patients with heart failure, and in triple therapy.
>
> The TGA has progressively reviewed the data on the safety of rosiglitazone as it has emerged and this has prompted the regulatory action already taken to date. While prescribing of the product has not been further restricted at this time and it has not been withdrawn from the market, the TGA's review of the safety of the product is ongoing.
>
> The TGA is also carefully reviewing the decisions of the EMA and FDA as part of its consideration of whether further regulatory action is warranted in Australia.

The TGA wishes to reinforce to prescribers the importance of the advice contained in the approved PI. A copy of the Boxed Warning is reproduced below.

> *The use of AVANDIA is not recommended in patients with known ischaemic heart disease, particularly in those taking nitrates. AVANDIA has been shown to be associated with an increased risk of myocardial ischaemia (angina, infarction) in pooled short-term clinical studies compared to combined active/placebo control (2.00% versus 1.53%, respectively), particularly in those who needed several antidiabetic drugs or nitrates.*
>
> *Any patients currently taking Avandia or Avandamet who have concerns should discuss these with their treating practitioner.*

The prescribing information approved in 2008 by the FDA was less restrictive than the current Australian prescribing information in the PI described above. On 23 September 2010 the FDA announced it was proposing to "significantly restrict" the use of these products by requiring the drug sponsor to submit a Risk Evaluation and Mitigation Strategy. These restrictions have yet to be implemented.

The European Medicines Agency has recommended the suspension of marketing authorisation for Avandia. The recommendation has been forwarded to the European Commission for the adoption of a legally binding decision. It is expected that Avandia will no longer be available in Europe within the next few months.

The TGA continues to work with its international regulatory counterparts at USFDA and EMA to ensure all relevant considerations that have led to the differing US and European positions have been considered in the TGA's regulatory action on this matter.