

6 July 2009

Clarification - Proposal to Reference Price Betaloc CR to AFT-Metoprolol CR

PHARMAC issued a consultation letter on 3 June 2009 regarding a proposal to reference price metoprolol succinate. The consultation included:

- information on the proposal to reduce the subsidy paid for Betaloc CR from 1 September 2009, so that it is the same as the subsidy paid for AFT-Metoprolol CR; and;
- background information, including information on the bioequivalence of AFT-Metoprolol CR and Betaloc CR, the physical differences between the two brands, manufacturing information and information on the fiscal effects of the proposal.

A respondent has raised concerns that the information provided regarding the bioequivalence of AFT-Metoprolol CR and Betaloc CR was deficient.

We wish to clarify that, in case of any confusion, the fed state comparative single dose bioequivalence study provided on page 3 of the consultation letter was for a 190mg dosage. We note further that the consultation letter did not provide details of the fasting or steady state bioequivalence studies that were also mentioned.

Comment

We note that background information on bioequivalence was:

- included to provide assurances that AFT-Metoprolol CR has been assessed by Medsafe for safety, bioequivalence and quality by comparison to Betaloc CR, and that Medsafe is satisfied that AFT-Metoprolol CR is safe, bioequivalent and of an appropriate quality;
- not included with the intention of giving a full breakdown on how bioequivalence was determined by Medsafe.

Medsafe, and not PHARMAC, is responsible for determining the bioequivalence of medicines registered for sale and supply in New Zealand. Should you have concerns about matters of safety, bioequivalence or quality for any medicine, these should be raised with Medsafe (see www.medsafe.govt.nz/other/contact.asp for contact details).

Feedback

PHARMAC continues to welcome feedback on its proposal to reference price Betaloc CR to AFT-Metoprolol CR. To provide feedback please submit it in writing by **5 pm on Friday 10th of July 2009** to:

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All feedback received before the closing date will be considered by PHARMAC's Board (or Chief Executive acting under delegated authority) prior to making a decision.