

5.20 PARACETAMOL tablet (modified release), 665 mg; Paracetamol Osteo- Tab[®]; AFT Pharmaceuticals Pty Ltd.

1 Purpose of Application

- 1.1 The minor submission sought a Restricted benefit listing for the relief of persistent pain associated with osteoarthritis.

2 Requested listing

- 2.1 The submission sought the same PBS listing as that applying to paracetamol with the trade name Pando Osteo[®] (item code: 8814X):

Name, Restriction, Manner of administration and form	Max. Qty	No.of Rpts	Proprietary Name and Manufacturer	
PARACETAMOL Paracetamol 665 mg tablet: modified release, 96 tablets	192	5	Paracetamol Osteo- Tab	AE

Restricted Benefit

Relief of persistent pain associated with osteoarthritis

3 Background

- 3.1 Paracetamol Osteo-Tab was TGA registered on 26 October 2012 and effective on 16 July 2014 for the relief of persistent pain associated with osteoarthritis.
- 3.2 Paracetamol tablet 665 mg (modified release) is currently PBS listed under the trade name of 'Panadol Osteo'.
- 3.3 Applications to list generic brands of products already listed on the PBS are usually processed by the Department without referral to the PBAC in circumstances where acceptance of bioequivalence or therapeutic equivalence by the TGA has been stated or where justification for not needing bioequivalence or therapeutic equivalence data has been provided to and accepted by the TGA.
- 3.4 The application to list paracetamol tablet 665 mg (modified release) with the brand 'Paracetamol Osteo-Tab' on the PBS failed to provide a statement from the TGA with respect to bioequivalence or therapeutic equivalence and hence the application was not processed as a generic brand submission by the Department but instead required consideration by the PBAC. The product had not previously been considered by the PBAC.

4 Clinical place for the proposed therapy

- 4.1 Paracetamol Osteo-Tab would provide an additional brand for patients with osteoarthritis.

5 Comparator

- 5.1 The minor submission nominated Panadol Osteo as the comparator.

6 Consideration of the evidence

Sponsor hearing

- 6.1 There was no hearing for this item as it was a minor submission.

Consumer comments

- 6.2 The PBAC noted that while no consumer comments were received through the Consumer Comments facility on the PBS website, one (1) organisation – GlaxoSmithKline Australia Pty Ltd, the sponsor of Panadol Osteo provided comments in support of not listing the product. Separate correspondence from Generic Partners Pty Ltd (agenda item 12.3) expressed the view that the nature of this submission to list a second paracetamol 665 mg modified release product warranted a major submission to the PBAC.

Clinical trials

- 6.3 The submission presented two unpublished single-dose pharmacokinetic studies in fast (Study #1) and fed (Study# 2) conditions and one unpublished multi-dose steady-state pharmacokinetic study (Study # 3) comparing Paracetamol Osteo- Tab with Panadol Osteo.
- 6.4 The basis of the minor submission's request was that Paracetamol Osteo-Tab is therapeutically equivalent to Panadol Osteo. However, a bioequivalence statement issued by the TGA was not provided in the submission.

Comparative effectiveness

- 6.5 The submission claimed that the results of the bioequivalence studies indicate that Panadol Osteo-Tab is therapeutically equivalent to Panadol Osteo.
- 6.6 The PBAC noted that no patient relevant outcome measures in terms of pain reduction or any other clinically meaningful measure of efficacy, were presented in the submission.

Comparative harms

- 6.7 No comparative harms data were presented in the submission.

Clinical claim

- 6.8 The submission claimed that Paracetamol Osteo-Tab is comparable to the originator product.

Economic analysis

- 6.9 The minor submission did not present a formal economic comparison.

Estimated PBS usage & financial implications

- 6.10 As the minor submission proposed a lower price (\$■■■■ ex-manufacturer) compared to the originator product (\$■■■■), the submission estimated that this would save PBS less than \$10 million per year assuming that the new product would take ■■■% of the market.

7 PBAC Outcome

- 7.1 The PBAC rejected the submission on the basis that no bioequivalence statement issued by the TGA had been provided and, in the absence of such a statement, the PBAC rejected the submission on the basis that no clinically relevant data had been presented to allow the PBAC to be sufficiently satisfied that the proposed product produces equivalent health outcomes as the existing product.
- 7.2 The PBAC noted that PBS listing is still be obtainable without the need for further PBAC reconsideration if the sponsor can provide a TGA issued bioequivalence statement in line with usual generic brand listing processes.
- 7.3 The PBAC noted that this submission is eligible for an Independent Review.

Outcome:

Rejected

8 Context for Decision

The PBAC helps decide whether and, if so, how medicines should be subsidised in Australia. It considers submissions in this context. A PBAC decision not to recommend listing or not to recommend changing a listing does not represent a final PBAC view about the merits of the medicine. A company can resubmit to the PBAC or seek independent review of the PBAC decision.

9 Sponsor's Comment

The Sponsor noted the PBAC comments and is conducting further work to address them.