

Public Summary Document

Product: Ferrous fumarate with folic acid, tablet, 310 mg –
350 micrograms, Ferro-F-Tab[®]
Sponsor: AFT Pharmaceuticals Pty Ltd
Date of PBAC Consideration: March 2006

1. Purpose of Application

The submission requested an unrestricted Pharmaceutical Benefits Scheme (PBS) listing for this combined iron with folic acid tablet.

2. Background

This particular presentation of iron/folic acid had not previously been considered by the Pharmaceutical Benefits Advisory Committee (PBAC).

Ferrous sulfate dried with folic acid, tablet, 250 mg-350 micrograms (sustained release) under the trade name F.G.F.[®] and sponsored by Abbott Australasia Pty Ltd was listed on the PBS in December 1972. The sponsor requested that F.G.F be de-listed from the PBS from 1 April 2005, stating that the product would not be discontinued and that the majority of the sales did not come through the PBS and F.G.F. is readily available through pharmacies at an average selling price of \$2.50.

3. Registration Status

Currently, the product is not registered by the TGA. However registration is expected in time for an 1 August 2006 listing.

4. Listing Requested and PBAC's View

Unrestricted listing

The PBAC considered the unrestricted listing appropriate.

5. Clinical Place for the Proposed Therapy

The submission stated that in the 12 months to February 2005 (inclusive), 330,000 prescriptions were processed for FGF tablets which, although modest, showed a reasonable need for such a product.

6. Comparator

The submission appropriately nominated FGF as the comparator.

7. Clinical Trials

The sponsor did not present any data from clinical trials

8. Results of Trials

The sponsor did not present any results from clinical trials.

However, the sponsors presented the following arguments in the submission:

- that there was a slight cost increase on a per tablet basis between the two products due to the following:
 - The higher elemental iron content and cost (100 mg versus 80 mg);
 - A gradual increase in raw material/packaging and associated costs since FGF was removed from the PBS;
 - The relatively low price of FGF.
- that this cost increase would be offset by the reduction in dispensing fees for a 60 versus 30 pack.

9. Clinical Claim

Not applicable. There was no need to make a clinical claim in this minor submission.

10. Economic Analysis

Not applicable. There was no need to include an economic analysis in this minor submission.

11. Estimated PBS Usage and Financial Implications

Not applicable for this minor submission.

12. Recommendation and Reasons

The PBAC recommended listing in view of the removal of FGF tablets from the PBS on 1 April 2005. The Committee considered it to be appropriate that such a product be available on the PBS to cater for concessional status patients with conditions requiring iron and folic acid supplementation. It was also noted that there was a need for this product by Indigenous Australians. Pricing should be based on the usual Pricing Authority criteria.

Ferrous fumarate with folic acid, tablet, 310 mg – 350 micrograms

Restriction: Unrestricted listing
Maximum Quantity: 60
Repeats: 1

13. 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.

14. Sponsor's Comment

The sponsor has no comment.