

**6.15 DABRAFENIB capsule, 50 mg & 75 mg, Tafinlar<sup>®</sup>  
TRAMETINIB tablet, 500 microgram & 2 mg,  
Mekinist<sup>®</sup>, Novartis Oncology**

**1 Purpose of Application**

- 1.1 The minor submission requested changing the restriction level for dabrafenib and trametinib from telephone Authority to STREAMLINED Authority.

**2 Requested listing**

- 2.1 The submission requested that the current General Schedule listing be changed from a telephone Authority to a STREAMLINED Authority. No change to the wording of the restriction was requested.

**3 Background**

- 3.1 Dabrafenib and trametinib are listed on the PBS for the treatment of BRAF-mutated type unresectable stage III or stage IV malignant melanoma.
- 3.2 The submission requested a STREAMLINED Authority listing to be consistent with the restriction level for other products available on the PBS for treatment of unresectable stage III and stage IV malignant melanoma (i.e. ipilimumab and pembrolizumab). Ipilimumab and pembrolizumab are infusible chemotherapy agents listed under Section 100 – Efficient Funding of Chemotherapy.
- 3.3 Trametinib is subject to a managed entry scheme. In regards to the managed entry scheme, the November 2014 PBAC minutes (para 7.9) states 'The PBAC proposed re-specifications of this [economic] model in a future evaluation, when the final data from the COMBI-V and COMBI-D trials are available to inform a revised model'. The Pre-PBAC response noted that pembrolizumab was also subject to a managed entry scheme.

**4 Consideration of the evidence**

**Sponsor hearing**

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

**Consumer comments**

- 4.2 The PBAC noted that no consumer comments were received for this item.

**Estimated PBS usage & financial implications**

- 4.3 The minor submission estimated there to be no changes in PBS utilisation of trametinib in combination with dabrafenib, nor the other agents (pembrolizumab or ipilimumab) as a consequence of altering dabrafenib and trametinib to a STREAMLINED Authority listing.

- 4.4 The submission stated that there are also [REDACTED] in place through existing [REDACTED], [REDACTED]

## **5 PBAC Outcome**

- 5.1 The PBAC recommended that the restriction levels of dabrafenib and trametinib be changed from Authority Required (telephone) to STREAMLINED Authority, noting that there were no changes to the content of the restriction wording.

### **Outcome:**

Recommended

## **6 Recommended listing**

- 6.1 Amend existing listing to STREAMLINED Authority.

## **7 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.

## **8 Sponsor's Comment**

The sponsor had no comment.